CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDTRONIC SPINE, LLC

I. PREAMBLE

Medtronic Spine, LLC, formerly known as Kyphon, Inc., (Kyphon) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote Kyphon's compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Kyphon is entering into a Settlement Agreement with the United States. This CIA shall apply only to U.S. operations of Kyphon that are subject to Federal health care program requirements.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Kyphon under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Kyphon's final annual report; or (2) any additional materials submitted by Kyphon pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all officers, directors, and employees of Kyphon;

b. all contractors, subcontractors, agents, and other persons who, on behalf of Kyphon, perform functions related to the sale or marketing of Reimbursable Items;

c. all employees of Medtronic Sofamor Danek, Inc. (MSD) (including, but not limited to, employees in Information Technology, Regulatory Affairs and Quality Assurance, Legal, Human Resources, Finance, and US Sales) who have responsibilities that directly support Kyphon in the sales or marketing of Reimbursable Items; and

d. all individuals who sell or market Reimbursable Items on behalf of Kyphon.

Notwithstanding the above, this term does not include part-time or per diem contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons who engage in, or supervise or train Covered Persons who engage in, the marketing or sale on behalf of Kyphon of Reimbursable Items and all Covered Persons who supervise, advise, or train Covered Persons who advise or train potential or actual customers and physician-users on use and reimbursement issues related to Reimbursable Items.

3. "Arrangements Covered Persons" includes all Covered Persons involved with the development, approval, management, or review of Kyphon's Arrangements, as such term is defined in Section II.C.6.

4. "Covered Items" means those items listed in Appendix A.

5. "Reimbursable Items" means Covered Items and all other items or services marketed by or on behalf of Kyphon for which reimbursement may be made directly or indirectly by the Federal health care programs.

6. "Arrangements" shall mean every arrangement or transaction entered into by or on behalf of Kyphon that: (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Kyphon or an entity on behalf of Kyphon and any actual or potential source of health care business or referrals to Kyphon or any actual or potential recipient of health care business or referrals from Kyphon. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing any good, facility, item, or service for which payment may be made in whole or in part, directly or indirectly, by a Federal health care program.

    a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to Kyphon, including, but not limited to, training, education, consulting, research, clinical studies, focus groups, and physician advisory boards; and intellectual property, grants, and charitable contributions.

    b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.

7. "Kyphon" shall mean the Medtronic Spine, LLC subsidiary of MSD and Medtronic, Inc. (Medtronic) (together the Medtronic Companies) and no other component or subsidiary of the Medtronic Companies.

III. CORPORATE INTEGRITY OBLIGATIONS

Kyphon shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* MSD represented to OIG that, prior to the Effective Date, MSD appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. MSD also represented that MSD's Compliance Officer has been appointed to serve as Kyphon's Compliance Officer. Kyphon shall continue to have a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of MSD or Kyphon, shall make periodic (at least quarterly) reports regarding compliance matters directly to MSD's Compliance Committee, and shall be authorized to report on such matters to the Executive Compliance Committee or the Audit Committee of Medtronic's Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of MSD or any other Medtronic Company. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Kyphon as well as for any reporting obligations created under this CIA.

Kyphon shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* MSD has represented to the OIG that, prior to the Effective Date of this CIA, MSD appointed a Compliance Committee of which the Compliance Officer and MSD's President are members. The Compliance Committee shall include the Compliance Officer, MSD's President, Kyphon's General Manager, and members of MSD senior management responsible for finance, clinical, human resources, legal, sales, and operations. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her

responsibilities (e.g., assist in the analysis of Kyphon's risk areas and oversee monitoring of internal and external audits and investigations).

Kyphon shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* The Medtronic Companies represented to the OIG that, prior to the Effective Date of this CIA, Medtronic developed a Code of Conduct ("the Code of Conduct"), which is applicable to Kyphon. Kyphon shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

a. the commitment to full compliance with all Federal health care program requirements;

b. the requirement that all Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with Kyphon's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this CIA);

c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Kyphon, suspected violations of any Federal health care program requirements or of Kyphon's own Policies and Procedures;

d. the possible consequences to both Kyphon and Covered Persons of failure to comply with Federal health care program requirements and with Kyphon's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and Kyphon's commitment to

nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 60 days after the Effective Date, Kyphon shall distribute to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Medtronic's Code of Conduct. Kyphon may distribute the Code of Conduct and required certification to each Covered Person either electronically or in hard-copy form. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 60 days after the Effective Date, whichever is later.

The Code of Conduct shall be periodically reviewed (at least annually) to determine if revisions are appropriate and shall be revised as necessary based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures*. Within 120 days after the Effective Date, Kyphon shall implement written Policies and Procedures regarding the operation of Kyphon's compliance program and its compliance with applicable Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. the Federal health care programs' use of reimbursement codes in identifying Reimbursable Items;

c. how to handle questions from Kyphon's customers or physician users regarding Federal health care program reimbursement for Reimbursable Items;

d. how to disseminate information regarding reimbursement for Reimbursable Items;

e. current sources of official guidance from Medicare contractors and the Centers for Medicare and Medicaid Services regarding reimbursement questions related to Reimbursable Items;

f. approved methods of promoting, marketing, and selling Reimbursable Items in accordance with Federal health care program requirements (Sales Policies and Procedures);

g. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.6; and

h. the requirements set forth in Section III.D, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of Arrangements.

The President of Kyphon shall review and approve all Sales Policies and Procedures and any material changes to Sales Policies and Procedures prior to their adoption, and shall review all Sales Policies and Procedures annually.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Kyphon's intranet or other internal web sites available to all employees. If Kyphon uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner, and it must adopt tracking procedures designed to track the distribution and ensure that all appropriate individuals receive the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Kyphon shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Kyphon shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain:

a. Kyphon's CIA requirements; and

b. Kyphon's Compliance Program (including Medtronic's Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.*

a. Reimbursable Items Training: Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Reimbursable Items Training. The Reimbursable Items Training shall include a discussion of:

i. appropriate methods of promoting, marketing, and selling Reimbursable Items in accordance with all Federal health care program requirements and the Policies and Procedures required by this CIA;

ii. the personal obligation of each Covered Person involved in the marketing and sales of Reimbursable Items to ensure that those products are marketed and sold in accordance with all applicable Federal health care program requirements;

iii. the personal obligation of each Covered Person involved in customer relations, reimbursement, sales, and marketing functions to know the applicable Federal health care program requirements and Kyphon's Policies and Procedures, and to ensure that customers are given accurate information regarding Kyphon's products, or redirected to payer resources;

iv. Medtronic's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Kyphon's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

v. applicable Federal health care program requirements; and

vi. the legal sanctions for violations of the Federal health care program requirements, and examples of such violations.

b. Anti-Kickback Training. Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Anti-Kickback Training. The Anti-Kickback Training shall include a discussion of:

i. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;

ii. Kyphon's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

iii. the personal obligation of each Arrangements Covered Person to know the applicable legal requirements and Kyphon's policies and procedures;

iv. the legal sanctions under the Anti-Kickback Statute; and

v. examples of violations of the Anti-Kickback Statute.

New Relevant Covered Persons and Arrangements Covered Persons shall receive the relevant Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons or Arrangement Covered Persons, or within 120 days after the Effective Date, whichever is later. A Covered Person who has completed the appropriate Specific Training shall review a new Relevant Covered Person's or Arrangement Covered Person's work, to the extent that the work relates to customer relations, reimbursement, sales, and marketing of Reimbursable Items or the development, approval, management, use, or review of Arrangements until such time as the new Relevant Covered Person or Arrangements Covered Person completes his or her Specific Training.

After receiving the Specific Training described in this Section III.C, each Relevant Covered Person shall receive at least two hours of Reimbursable Items Training and each Arrangements Covered Person shall receive at least two hours of Anti-Kickback Training in each subsequent Reporting Period.

3. *Certification.* Each Covered Person who is required to attend training pursuant to this Section III.C shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* Kyphon shall review annually the training programs developed to satisfy the requirements of this Section III.C, and, where appropriate, update the training to reflect changes in applicable Federal health care program requirements,

any issues discovered during internal audits, the Sales and Marketing Review, the Arrangements Review, and any other relevant information.

6. *Training Methods.* Kyphon may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If Kyphon chooses to provide training pursuant to any such method, it shall make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Kyphon shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to the Anti-Kickback Statute (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix B (Arrangements Database);

b. tracking remuneration to and from all parties to Arrangements;

c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);

d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);

e. establishing and implementing a written review and approval process for all Contractual Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the

purpose of which is to ensure that all new and existing or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not limited to an annual legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all Non-Contractual Arrangements do not violate the Anti-Kickback Statute;

g. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

h. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Arrangements*. Prior to entering into new Contractual Arrangements or renewing existing Contractual Arrangements, in addition to complying with the Arrangements Procedures set forth above, Kyphon shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Kyphon and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Kyphon's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, Kyphon shall provide each party to the Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures; and

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* Kyphon shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section III.D and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Kyphon shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Kyphon in assessing and evaluating its sales and marketing systems, processes, policies, and procedures (the Sales and Marketing Review) and to perform a review to assist Kyphon in assessing its compliance with the obligations pursuant to Section III.D of this Agreement (Arrangements Review).

Each IRO shall assess, along with Kyphon, whether it can perform the IRO reviews in a professionally independent and objective fashion, as appropriate to the nature of the engagements, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO shall not be deemed to create an attorney-client relationship between MSD or Kyphon and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix C to this CIA, which is incorporated by reference.

b. *Frequency of Sales and Marketing Review.* The Sales and Marketing Review shall be performed annually and shall cover each

of the Reporting Periods. The IRO(s) shall perform all components of each Review.

c. *Frequency of Arrangements Review.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

d. *Retention of Records.* The IRO(s) and Kyphon shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Kyphon) related to the engagements.

e. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Kyphon's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

f. *Mitigation of the Arrangements Review.* After the submission of the third Arrangements Review Report, Kyphon may request to be released from the Arrangements Review for the remaining period of the CIA. The OIG may, at its sole discretion, grant Kyphon's request.

2. *Sales and Marketing Engagement.*

a. *The Sales and Marketing Review.* The IRO shall perform a Sales and Marketing Review to assist Kyphon in assessing and evaluating its systems, processes, policies, and procedures related to the sales and marketing of Reimbursable Items. Prior to performing the Sales and Marketing Review, the IRO shall submit its workplan to the OIG for approval. If OIG does not provide comments or recommendations within 60 days, the IRO's workplan for that Reporting Period will be deemed approved. Any comments or recommendations made by the OIG in connection with a review of the submitted workplan shall not preclude the OIG from making

further comments or recommendations for future workplan(s) after reviewing the Sales and Marketing Report. The objectives of the Sales and Marketing Review shall be to examine the accuracy of information provided by Kyphon to its customers and physician users relating to Federal health care program reimbursement, if any, for its Reimbursable Items.

b. *Sales and Marketing Review Report.* The IRO shall prepare a report based upon each Sales and Marketing Review performed (Sales and Marketing Review Report). At a minimum, the Sales and Marketing Review Report shall include: (i) a clear statement of the objective intended to be achieved by the Sales and Marketing Review; (ii) a description of the specific documentation relied upon and individuals interviewed by the IRO when performing its review; (iii) a narrative description of how the Sales and Marketing Review was conducted; (iv) the results, conclusions, and recommendations developed by the IRO based upon the review performed; and (v) the names and credentials of the individuals who performed the Sales and Marketing Review.

3. *The Arrangements Engagement.*

a. *Arrangements Review.* The IRO shall perform a review to assess whether Kyphon is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 40 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Kyphon has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Kyphon has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (i) verifying that the Arrangement is listed in the Arrangements Database; (ii) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is

appropriately documented; (iii) verifying that the remuneration related to the Arrangement is properly tracked; (iv) verifying that the service and activity logs are properly completed and reviewed (if applicable); (v) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (vi) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (vii) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute are discovered; and (viii) verifying that Kyphon has met the requirements of Section III.D.2.

b. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (i) whether Kyphon has generally implemented the Arrangements Procedures described in Section III.D.1; and (ii) specific findings as to whether Kyphon has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include any observations, findings, and recommendations on possible improvements to Kyphon's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

4. *Validation Review.* In the event OIG has reason to believe that: (a) Kyphon's Sales and Marketing Review or Arrangements Review fails to conform to the requirements of this CIA; or (b) the IRO's findings, Sales and Marketing Review, or Arrangements Review are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Sales and Marketing Review or Arrangements Review complied with the requirements of the CIA and/or the findings or Sales and Marketing Review or Arrangements Review are inaccurate (Validation Review). Kyphon shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Kyphon's final Annual

Report shall be initiated no later than one year after Kyphon's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Kyphon of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Kyphon may request a meeting with OIG for one or more of the following reasons: (a) to discuss the results of any Sales and Marketing Review, Arrangements Review, or both; (b) to present any additional information to clarify the results of the Sales and Marketing Review, the Arrangements Review, or both, or to correct the inaccuracy of the Sales and Marketing Review, the Arrangements Review, or both; or (c) to propose alternatives to the proposed Validation Review. Kyphon agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any Sales and Marketing Review or Arrangements Review issues with Kyphon prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* Each IRO shall include in its report(s) to Kyphon a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Sales and Marketing Review, the Arrangements Review, or both, and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

MSD has represented to the OIG that, prior to the Effective Date of this CIA, it established a Disclosure Program that includes a toll-free compliance telephone line to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Kyphon's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. To the extent not already accomplished, Kyphon shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). Kyphon shall continue the Disclosure Program during the Term of the CIA as set forth in this Section III.F.

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good-faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Kyphon shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a confidential Kyphon disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include all current owners (other than shareholders who: (i) have an ownership interest of less than 5%; and (ii) acquired the ownership interest through public trading), all current and prospective officers, directors, employees, contractors, and agents of Kyphon who perform functions related to the delivery, sale, or marketing of Reimbursable Items, and all officers, directors, and employees of MSD who perform functions related to the sale or marketing by Kyphon of Reimbursable Items.

2. *Screening Requirements.* Kyphon shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Kyphon shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons. Kyphon shall also screen all prospective owners prior to acquisition (other than shareholders who: (i) will have an ownership interest of less than 5%; and (ii) will acquire the ownership interest through public trading).

b. Kyphon shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Kyphon shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.