SETTLEMENT AGREEMENT

I. <u>PARTIES</u>

This Settlement Agreement (the "Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively the "United States"), and Boston Scientific Corporation ("BSC") (hereafter referred to as "the Parties"), through their authorized representatives.

II. <u>PREAMBLE</u>

As a preamble to this Agreement, the Parties agree to the following:

A. Guidant Corporation ("Guidant") manufactured and sold several types of cardiac rhythm management ("CRM") devices, including pacemakers, implantable cardioverter defibrillator ("ICD") devices, and cardiac resynchronization therapy ("CRT") devices. In April 2006, BSC acquired Guidant.

B. The United States contends that Guidant submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh.

C. The United States contends that it has certain civil and administrative claims, as specified in Paragraph III.B, below, against BSC for the following conduct during the years 2003 and 2004 (hereinafter referred to as the "Covered Conduct"):

Guidant used four post-market studies known as "RaCE" (hereinafter, "RaCE I"), "RaCE II," "RaCE III," and "MERITS" (together, the "Subject Studies") as vehicles to pay participating physicians kickbacks to implant Guidant CRM devices. Ostensibly, Guidant designed the Subject Studies to obtain feedback from participating physicians who implanted Guidant CRM devices. In fact, Guidant knowingly and intentionally designed and used the Subject Studies as a means of increasing device sales by paying physicians to select Guidant CRM devices to implant in their patients rather than devices manufactured by Guidant's competitors. Each of the Subject Studies required participating physicians to implant multiple Guidant CRM devices (five devices per physician in RaCE I and three devices per physician in RaCE II, RaCE III, and MERITS), and, in each study, Guidant paid each participating physician a fee (\$1,500 in RaCE I, and \$1,000 in RaCE II, RaCE III, and MERITS). In many of the Subject Studies, Guidant targeted physicians whom Guidant believed to favor competing companies' CRM devices; Guidant chose these physicians because it believed the fees associated with participation in the Subject Studies would cause the physicians to switch some of their business to Guidant.

D. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below. BSC expressly denies liability, and this Agreement is neither an admission of facts or liability by BSC nor a concession by the United States that its claims are not well founded.

III. TERMS AND CONDITIONS

A. BSC agrees to pay to the United States \$22 million plus interest in an amount of 3.25% per annum from July 1, 2009, and continuing until and including the day before complete payment is made (the "Settlement Amount"). BSC agrees to pay the Settlement Amount to the United States by electronic funds transfer pursuant to written instructions to be provided by the

U.S. Attorney's Office for the District of Massachusetts. BSC agrees to make this electronic funds transfer no later than seven (7) calendar days after the Effective Date of this Agreement.

B. Subject to the exceptions in Paragraph III.D (concerning excluded claims), below, in consideration of the obligations of BSC in this Agreement, conditioned upon BSC's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release BSC, its directors, officers, employees, and agents, together with its current and former parent corporations, direct and indirect subsidiaries, divisions, current or former owners, and the successors and assigns of any of them, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, or the common law theories of unjust enrichment and fraud.

C. In consideration of the obligations of BSC in this Agreement and the Corporate Integrity Agreement entered into between BSC and OIG-HHS, conditioned upon BSC's full payment of the Settlement Amount, OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against BSC under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph III.D (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude BSC from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph III.D, below.

D. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including BSC) are the following claims of the United States:

Any civil, criminal, or administrative liability arising under Title 26,
United States Code (Internal Revenue Code);

2. Any criminal liability;

3. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

4. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

5. Any liability based upon such obligations as are created by this Agreement;

6. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

7. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and

8. Any liability for failure to deliver goods or services due.

E. BSC waives and shall not assert any defenses BSC may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole

or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

F. BSC fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that BSC has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

G. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

H. BSC agrees to the following:

1. <u>Unallowable Costs Defined</u>: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47, and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of BSC, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):

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a. the matters covered by this Agreement;

b. the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;

c. BSC's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

d. the negotiation and performance of this Agreement;

- e. the payment BSC makes to the United States pursuant to this Agreement, including costs and attorneys fees; and
 - f. the negotiation of, and obligations undertaken pursuant to the CIA
 - (i) retain an independent review organization to perform

annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to OIG-HHS.

However, nothing in this paragraph H.1.f that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to BSC. (All costs described or set forth in this Paragraph H.1 are hereafter "Unallowable Costs.")

2. <u>Future Treatment of Unallowable Costs</u>: These Unallowable Costs shall be separately determined and accounted for by BSC, and BSC shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid

to:

program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by BSC or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

3. <u>Treatment of Unallowable Costs Previously Submitted for Payment</u>: BSC further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by BSC or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. BSC agrees that the United States, at a minimum, shall be entitled to recoup from BSC any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by BSC or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on BSC or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

4. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine BSC's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

I. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and BSC agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

J. BSC agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, BSC shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage the cooperation of, former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals.

K. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

L. BSC agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

M. BSC represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

N. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the District of Massachusetts, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.

O. For purposes of construction, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

P. This Agreement and the CIA constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

Q. The individuals signing this Agreement on behalf of BSC represent and warrant that they are authorized by BSC to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

R. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

S. This Agreement is binding on BSC's successors, transferees, heirs, and assigns.

T. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

U. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

BY:

C

THE UNITED STATES OF AMERICA

DATED: 12/23/09

BY: GRECC SHAPIRO DONALD J. SAVERY Assistant United States Attorneys

District of Massachusetts

DATED:

GREGORY E. DEMSKE Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human Services

Settlement Agreement Between United States And Boston Scientific Corporation

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BOSTON SCIENTIFIC CORPORATION

DATED: 12/22/09

Elliott ROK BY: J. RAYMOND ELLIOTT

President, Chief Executive Officer, and Chief Operating Officer

DATED:_____

BY:

ROBERT D. KEEFE Wilmer Cutler Pickering Hale and Dorr LLP

GARY W. THOMPSON Akin Gump Strauss Hauer & Feld LLP

Counsel for Boston Scientific Corporation

Settlement Agreement Between United States And Boston Scientific Corporation

BOSTON SCIENTIFIC CORPORATION

DATED:_____

DATED: 12/22/09

BY:

J. RAYMOND ELLIOTT President, Chief Executive Officer, and Chief Operating Officer

BY:

ROBERT D. KEEFE ' U Wilmer Cutler Pickering Hale and Dorr LLP

GARY W. THOMPSON Akin Gump Strauss Hauer & Feld LLP

Counsel for Boston Scientific Corporation

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BOSTON SCIENTIFIC CORPORATION

DATED:_____

J. RAYMOND ELLIOTT President, Chief Executive Officer, and Chief Operating Officer

DATED:_____ BY:

12/22/09

and Chief Operating Officer

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BY:

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Akin Gump Strauss Hauer & Feld LLP

Counsel for Boston Scientific Corporation

Settlement Agreement Between United States And Boston Scientific Corporation

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