

United States District Court

District of Minnesota

UNITED STATES OF AMERICA

v.

Guidant LLC**JUDGMENT IN A CRIMINAL CASE**

(For Organizational Defendants)

Case Number: **10-MJ-67 DWF**Federal Employer I.D. No. **04-2695240****Daniel M. Scott**

Defendant Organization's Attorney

THE DEFENDANT ORGANIZATION:

- ☒ pleaded guilty to count(s): **1 & 2 of the Misdemeanor Information.**
- ☐ pleaded nolo contendere to counts(s) which was accepted by the court.
- ☐ was found guilty on count(s) after a plea of not guilty.
- The organizational defendant is adjudicated is guilty of the following offenses:

<u>Title & Section</u>	<u>Nature of Offense</u>	<u>Offense Ended</u>	<u>Count</u>
Title 21 §§ 331(q)(2), 360i and 333(a)(1)	Submission of False and Misleading Report to FDA	August 19, 2003	1
Title 21 §§ 331(q)(1)(B), 360i(g) and 333(a)(1)	Failure and Refusal to Report Medical Device Correction	March 2, 2005	2

The defendant organization is sentenced as provided in pages 2 through 6 of this judgment.

- ☐ The defendant organization has been found not guilty on counts(s) .
- ☐ Count(s) (is)(are) dismissed on the motion of the United States.

The Special Assessment in the amount of **\$250.00** shall be paid in full immediately.

It is ordered that the defendant organization must notify the United States attorney for this district within 30 days of any change of name, principal business address, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant organization shall notify the court and United States attorney of material changes in economic circumstances.

January 12, 2011

Date of Imposition of Judgment

s/Donovan W. Frank

Signature of Judicial Officer

DONOVAN W. FRANK, United States District Judge

Name & Title of Judicial Officer

January 13, 2011

Date

DEFENDANT ORGANIZATION: GUIDANT LLC

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PROBATION

The defendant organization is hereby sentenced to probation for a term of **3 years on Counts 1 and 2 to run concurrent. Given Guidant LLC's and Boston Scientific's participation in the 2009 Corporate Integrity Agreement as well as Boston Scientific's Global Compliance Program, each of which has been implemented since the conduct that gave rise to the case before the Court, the Court will review on a yearly basis whether it should grant an early discharge from probation of Guidant LLC.**

The defendant organization shall not commit another federal, state or local crime.

If this judgment imposes a fine or a restitution obligation, it is a condition of probation that the defendant organization pay in accordance with the Schedule of Payments sheet of this Judgment.

The defendant organization must comply with the standard conditions that have been adopted by this court as well as with any additional conditions on the attached page (if indicated below).

STANDARD CONDITIONS OF SUPERVISION

- 1) within thirty days from the date of this judgment, the defendant organization shall designate an official of the organization to act as the organization's representative and to be the primary contact with the probation officer;
- 2) the defendant organization shall answer truthfully all inquiries by the probation officer and follow instructions of the probation officer;
- 3) the defendant organization shall notify the probation officer ten days prior to any change in principal business or mailing address;
- 4) the defendant organization shall permit a probation officer to visit the organization at any of its operating business sites;
- 5) the defendant organization shall notify the probation officer within seventy two hours of any criminal prosecution, major civil litigation, or administrative proceeding against the organization;
- 6) the defendant organization shall not dissolve, change its name, or change the name under which it does business unless this judgment and all criminal monetary penalties imposed by this court are either fully satisfied or are equally enforceable against the defendant's successors or assignees; and
- 7) the defendant organization shall not waste, nor without permission of the probation officer, sell, assign, or transfer its assets.

DEFENDANT ORGANIZATION: GUIDANT LLC

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ADDITIONAL PROBATION TERMS

- a Guidant LLC shall forfeit \$42,079,675.00. Pursuant to the plea agreement, Guidant LLC has agreed to pay the full amount within 10 business days after the Court approves the plea agreement.
- b Guidant LLC shall not commit any crimes, federal, state, or local.
- c Guidant LLC shall, at the direction of the U.S. Probation and Pretrial Services Office, make periodic submissions reporting on Guidant LLC's financial condition.
- d Guidant LLC shall submit to a reasonable number of regular or unannounced examinations of its books and records by the U.S. Probation and Pretrial Services Office or experts engaged by the Court and interrogation of knowledgeable individuals within the organization. Compensation to and costs of any experts engaged by the Court shall be paid by the organization.
- e Guidant LLC shall be required to notify the U.S. Probation and Pretrial Services Office immediately upon learning of any material adverse change in its financial condition or any investigation or formal inquiry regarding the organization or any litigation, criminal prosecution, or administrative proceeding against the organization.
- f Guidant LLC shall, no later than 30 days after the close of each calendar quarter, provide the following to the U.S. Probation and Pretrial Services Office:
 - i. Approvals or modifications to approvals by the FDA of the company's tachycardia devices;
 - ii. Product performance reports on company products;
 - iii. Establishment Inspection Reports (EIR's) received by the company;
 - iv. Notices of inspections or audits by the FDA relating to tachycardia devices;
 - v. Product advisories relating to tachycardia devices;
 - vi. Market withdrawal notices by the company of tachycardia devices;
 - vii. Field communications regarding tachycardia devices; and
 - viii. Subpoenas received by the company relating to tachycardia devices.
- g Guidant LLC shall comply with the recommendations and requirements of the Court with respect to ensuring that any compliance program will adequately prevent or detect any further violations of law.
- h Guidant LLC shall designate reasonable corporate officers, including a corporate officer at the Boston Scientific headquarters in Arden Hills, Minnesota, to be personally responsible for implementing and overseeing the fulfillment of the conditions of probation.

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ADDITIONAL PROBATION TERMS

(continued from previous page)

- i Guidant LLC, under the voluntary leadership of Boston Scientific, has agreed to continue to provide community education efforts to increase the awareness of cardiovascular risk factors through a variety of community programs and, by doing so, identifying and helping high-risk patients. The Court would request that this include, under the leadership of Boston Scientific, a continuation of their social media campaign, through Facebook, Twitter and YouTube, and embarking on a pilot project with the American Heart Association. The Court incorporates by reference the description provided by Boston Scientific and Guidant LLC of the Close the Gap program and the science, technology, engineering, and mathematics (STEM) education in pages 19 through 26 of Defendant's sentencing submission. (Attached as Exhibit A.) The Court directs that Guidant LLC, under the voluntary leadership of Boston Scientific, continue the Close the Gap's objective to achieve parity, in no more than ten years, in the treatment of cardiovascular disease in historically underserved patient populations; specifically women, African-Americans and Hispanic/Latino Americans.
- j Guidant LLC, under the voluntary leadership of Boston Scientific, shall continue its funding for its science, technology, engineering, and mathematics (STEM) initiative. Guidant LLC shall provide proof of this continued funding at the end of each calendar year to the U.S. Probation and Pretrial Services Office. The Court would note that Guidant LLC, under the leadership of Boston Scientific, has agreed to continue their community service commitment by increasing funding for the Close the Gap and STEM education initiatives by providing a total of \$15,000,000.00 for these two community education initiatives over the next three years.
- k Guidant LLC shall notify its employees and shareholders of its behavior in this case and its Global Compliance program.

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CRIMINAL MONETARY PENALTIES

The defendant organization must pay the following total criminal monetary penalties under the Schedule of Payments on Sheet 4.

	<u>Assessment</u>	<u>Fine</u>	<u>Restitution</u>
Totals:	\$250.00	\$253,962,251.00	NA

☐ The determination of restitution is deferred until . *An Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant organization shall make restitution (including community restitution) to the following payees listed below.

If the defendant organization makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. §3664(i), all nonfederal victims must be paid before the United States is paid.

Name and Address of Payee	**Total Amount of Loss	Restitution Ordered	Priority or Percentage
NA			
TOTALS:	\$0.00	\$0.00	0.00%
Payments are to be made to the Clerk, U.S. District Court, for disbursement to the victim.			

☐ Restitution amount ordered pursuant to plea agreement \$.

☐ The defendant organization shall pay interest on restitution or a fine of more than \$2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of judgment, pursuant to 18 U.S.C. §3612(f). All of the payment options on Sheet 4 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. §3612(g).

☐ The court determined that the defendant organization does not have the ability to pay interest, and it is ordered that:

☒ the interest requirement is waived for the ☒ fine ☐ restitution as Guidant LLC has agreed to pay the full amount within 10 business days after the court approves the plea agreement.

☐ the interest requirement for the: ☐ fine ☐ restitution is modified as follows:

** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 United States Code, for offenses committed on or after September 13, 1994 but before April 23, 1996.

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SCHEDULE OF PAYMENTS

Having assessed the organization's ability to pay, payment of the total criminal monetary penalties shall be due as follows:

- A ☐ Lump sum payment of \$ due immediately, balance due
- ☐ not later than , or
☐ in accordance with ☐ C or ☐ D below; or
- B ☐ Payment to begin immediately (may be combined with ☐ C or ☐ D below); or
- C ☐ Payment in (e.g., equal, weekly, monthly, quarterly) installments of \$ over a period of (e.g. months or years), to commence (e.g. 30 or 60 days) after the date of this judgment; or
- D ☒ Special instructions regarding the payment of criminal monetary penalties: Payments are to be made payable to the Clerk, U.S. District Court.

All criminal monetary penalties are to be made to the clerk of court.

The defendant organization shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several
Defendant and Co Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate:

☐ The defendant organization shall pay the cost of prosecution.

☐ The defendant organization shall pay the following court costs(s):

☐ The defendant organization shall forfeit the organization's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.