DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139	08/25/2005 - 09/12/2005* FEI NUMBER 1828132

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. George Telthorst, General Manager

FIRM NAME	STREET ADDRESS
Boston Scientific Corp	780 Brookside Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Spencer, IN 47460-1080	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, Complaints are received by the Boston Scientific Complaint Call Center, who then forwards the complaint to the appropriate Complaint Management Center (CMC), where an initial MDR determination is completed. The CMC then has the Complaint Investigation Site, the site that manufactured the device, conduct a complaint investigation to determine root cause and search for complaint trends. The following complaints were determined to be MDR reportable by Boston Scientific Corporation, however, the MDR reports were filed more than 30 days after the initial complaint notification.

Complaint #	Date	MDR Date	MDR #	Total Days to Report
656079	4/12/05	5/27/05	6000048-2005-00069	45
650818	12/9/05	1/28/05	6000048-2005-00011	50
658865	6/20/05	8/10/05	6000048-2005-00100	51
652641	1/31/05	7/25/05	6000043-2005-00028	176
655395	4/1/05	6/30/05	6000043-2005-00021	90
654226	2/28/05	6/30/05	6000043-2005-00020	122
646103	8/16/04	2/10/05	6000043-2005-00002	178
647525	9/21/04	2/10/05	6000043-2005-00008	142
645897	8/2/04	2/10/05	6000043-2005-00003	192
649232	11/1/04	1/28/05	6000048-2005-00013	91
655419	4/4/05	6/30/05	6000043-2005-00023	90
652411	1/25/05	3/21/05	6000043-2005-00014	55
646545	8/25/04	2/28/05	6000043-2005-00006	84

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648630	10/18/042/28/05	6000043-2005-00005	41
647742	9/27/04 2/28/05	6000043-2005-00004	154
627223	5/7/05 6/30/05	6000043-2005-00022	54

OBSERVATION 2

Complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

Specifically,

a) The LeVeen Needle Electrode recall investigation was incomplete. BSC Spencer, the manufacturer of the LeVeen Needle Electrode, which is used as an accessory in conjunction with the Boston Scientific Corporations Radiofrequency (RF) generator for thermal necrosis of soft tissues, was not aware of the LeVeen Needle Electrode recall when the FDA Investigator asked for that specific recall documentation. By not being aware of the LeVeen Needle Electrode recall and the subsequent investigation activities, the firm can not assure that a complete recall investigation was conducted on both the LeVeen Needle Electrode, manufactured at BSC Spencer, and the BSC RF generator. The product investigation report is WAT-2005-04-01. The LeVeen Needle Electrode affected model numbers are M001262160 and M001262170.

b) BSC Spencer has the capability to do trending analysis by product lot number and product part number. For 7 of 15 complaints reviewed specific to the Leveen Electrode recall, Part #M001262160 and M001262170, Complaints 656988, 654015, 654019, 654023, 654029, 654032, 654033 the device was not returned and the complainant did not give the lot number. The complaint investigation was incomplete in that the firm did not investigate each complaint completely to identify possible trends. For these seven complaints, the lot number was not available and there was no trending analysis done on the LeVeen product number.

OBSERVATION 3

Complaint handling procedures for reviewing and evaluating complaints have not been completed.

Specifically, BSC Spencer External Customer Complaint Process procedure, #90101079 is incomplete in that it does not identify all trending types to be researched during the failure analysis to determine if their are any related complaints. For 7 of 15 complaints reviewed specific to the Leveen Electrode recall, the firm did not do trending by product part number for complaint investigations when the device was not returned and the firm was unable to obtain the product lot number. The complaints were closed after 90 days.

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OBSERVATION 4

Procedures for the control and distribution of finished devices have not been defined and complete to ensure that only devices approved for release are distributed.

Specifically, when BSC Spencer places a shipping hold on products, they can still ship product from their facility to the BSC Quincy distribution facility "at risk" and on ship hold. The BSC Spencer procedure, Shipping Holds - In-plant and Distribution Holds, Q489027-0A, does not require the firm to hold product at the BSC Spencer facility.

*** DATES OF INSPECTION:**
08/25/2005(Thu), 08/26/2005(Fri), 08/29/2005(Mon), 08/30/2005(Tue), 09/02/2005(Fri), 09/06/2005(Tue), 09/09/2005(Fri), 09/12/2005(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Benjamin J Smith, Investigator

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