DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
212 3rd Ave. South Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134	07/22/2005 - 08/25/2005* FEI NUMBER 3002095335

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Aaron P. Milton, Vice President Operations

FIRM NAME	STREET ADDRESS
Boston Scientific Scimed	1 Scimed Pl
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Maple Grove, MN 55311-1565	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 WE 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 may have caused or contributed to a death or serious injury.

Specifically, from January 2004 to June 2005, 66 MDR reports of death or serious injury were not submitted within 30 days.

Annotation: Promised to correct.

OBSERVATION 2

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, from January 2004 to June 2005, 36 MDR reports of malfunction were not submitted within 30 days.

Annotation: Promised to correct.

OBSERVATION 3

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by a designated individual.

Specifically, complaints of serious injury, death, or malfunction were not always evaluated with regard to the prompt filing of

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MDR reports. From January 2004 to June 2005, as a result of human error, 46 events were filed late as MDR reports.

Annotation: Promised to correct.

OBSERVATION 4

The procedures for implementing corrective and preventive actions were not implemented.

Specifically, a corrective and preventive action was not initiated on the recurring situation of MDR reports being submitted late.

Annotation: Promised to correct.

OBSERVATION 5

Procedures for acceptance or rejection of finished device production runs, lots, or batches were not complete.

Specifically, the Relative Humidity specification range at [redacted] is established more broadly ([redacted] RH) than the actual applied process range (approximately [redacted] RH). Procedures do not describe steps to take, should this parameter change from the routinely applied range.

Annotation: Under consideration.

*** DATES OF INSPECTION:**
07/22/2005(Fri), 07/25/2005(Mon), 07/26/2005(Tue), 07/27/2005(Wed), 07/28/2005(Thu), 07/29/2005(Fri), 08/01/2005(Mon), 08/02/2005(Tue), 08/03/2005(Wed), 08/04/2005(Thu), 08/08/2005(Mon), 08/09/2005(Tue), 08/11/2005(Thu), 08/23/2005(Tue), 08/25/2005(Thu)

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Jocelyn M. Muggli, Investigator

Ralph W. Jerndal, Investigator

Billi Jo M. Johnson, Investigator

SEE REVERSE OF THIS PAGE	This is a modified document.	DATE ISSUED 08/25/2005