BOSTON SCIENTIFIC CORP
Form 8-K
April 15, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): April 15, 2010

BOSTON SCIENTIFIC CORPORATION
(Exact name of registrant as specified in charter)

DELAWARE	1-11083	04-2695240
(State or other jurisdiction of incorporation)	(Commission file number)	(IRS employer identification no.)

One Boston Scientific Place, Natick, Massachusetts	01760-1537
(Address of principal executive offices)	(Zip code)

Registrant's telephone number, including area code: (508) 650-8000

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

ITEM 8.01. OTHER EVENTS.

Today we announced that we have received U.S. Food and Drug Administration (FDA) clearance for the two validated manufacturing changes affecting all of our cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs), and that we will immediately resume distribution of our COGNIS® CRT-Ds and TELIGEN® ICDs. We are positioned to fully meet customer demand for COGNIS and TELIGEN within 24 hours. COGNIS and TELIGEN represent virtually all of our defibrillator implant volume in the United States.

On March 15th and 16th we submitted the two manufacturing changes to the FDA for the following CRT-D and ICD product families: COGNIS, TELIGEN, CONFIENT™, LIVIAN™, PRIZM™, RENEWAL® and VITALITY™. Solely on ou own initiative we conducted an internal review of manufacturing and other changes for these products, as well as the associated regulatory submissions. The review found a few additional instances where we did not submit the appropriate documentation for validated manufacturing changes. We have now submitted this documentation and are working closely with the FDA to secure clearances to return CONFIENT, LIVIAN, PRIZM, RENEWAL and VITALITY, the earlier generations of our CRT-D and ICD products, to market as soon as possible in the United States. These products may continue to be implanted in geographies outside the United States.

Our pacemakers and other products were not affected by the ship hold and product removal actions. Geographies outside the United States were never affected, and remain unaffected, by these actions.

A copy of the press release and related communications are furnished as exhibits hereto.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

Exhibit No.	Description
Exhibit 99.1:	Press Release dated April 15, 2010.
Exhibit 99.2:	Letter to Physicians.
Exhibit 99.3:	Letter to Patients.

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BOSTON SCIENTIFIC CORPORATION

Date: April 15, 2010

By: /s/ Lawrence J. Knopf
Lawrence J. Knopf
Senior Vice President and Deputy General Counsel

EXHIBIT INDEX

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