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JAN 6, 1997

Boston Scientific Corporation

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510(k) Summary

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification ". . . adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

Trade Name: **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System**

Manufacturer: Boston Scientific Corporation
480 Pleasant Street
Watertown, MA 02172

Device Generic Name: Guidewire for Vena Cava Filter System

Classification:

According to Section 513 of the Federal Food, Drug and Cosmetic Act, FDA has classified cardiovascular intravasuclar filters in Class III, 21 CFR § 870.3375, under guidance by the Circulatory Systems Devices Panel. Although 21 CFR § 870.3375 requires premarket approval for cardiovascular intravascualr filters, no effective date has been established for the reqirement of PMA's for these devices at this time.

Predicate Device: **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System**

Device Description:

The **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System** consists of sequential vascular dilators for percutaneous access; a guidewire to guide the Introducer Sheath and Dilator into place; an Introducer Sheath and Dilator to create a passageway to guide the Introducer Catheter to the implant site; and an Introducer Catheter to transport the pre-loaded filter through the sheath and over the guidewire to the implant site for filter deployment .

Indications For Use:

The **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System** is indicated for the prevention of pulmonary embolism via placement in the vena cava in the following situations:

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- Venous thrombosis or pulmonary thromboembolism when anticoagulants are contraindicated or inadequate for management of venous thrombosis with significant risk of, or following, pulmonary thromboembolism.
- Failure of anticoagulant therapy in thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

Contraindications:

Patients in whom the diameter of the inferior vena cava exceeds 28 mm are contraindicated for the placement of the **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System**.

- Presence of thrombus at the femoral puncture site, in the iliac vein, or in the inferior vena cava risks the dislodgement of thrombus during catheter manipulation.
- Patients in whom pregnancy has been confirmed.

Safety and Performance:

Bench and Animal testing were performed and the data supported the substantial equivalence of the proposed guidewire for the ***Jugular*** **Stainless Steel Greenfield ® Vena Cava Filter with 12F Introducer System** to the current guidewire of the ***Jugular*** **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System**.

The biocompatibility of the **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System (K912035)** was previously established through biocompatibility testing performed on the predicate in accordance with the Tripartite Biocompatibility Guidance (#G87-1). This testing is also in accordance with blue book memorandum #G95-1, "Use of International Standard ISO-10993, Biologicaly Evaluation of Medical Devices Part 1: Evaluation and Testing with FDA-modified matrix.

Conclusion:

Based upon the indications for use, technological characteristics, and safety and performance testing, the guidewire for the ***Jugular*** **Stainless Steel Greenfield® Vena Cava Filter with 12F Introducer System** meets the requirements for its intended use.