SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K013789

a. Date Prepared: November 09, 2001

DEC 0 6 2001

b. Contact Person

George J. Prendergast
Regulatory Affairs Specialist II
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

c. Trade Name

Excelsior™SL-10 Microcatheter

d. Common Name

Microcatheter

e. Classification Name

Percutaneous Catheter (21 CFR Section 870.1250)

f. Identification of Predicate Devices

Number	Description	Clearance Date
K994155	Excelsior 1018 Microcatheter	03 August 2000
K925813	Tracker-10 Microcatheter	23 March 1994

g. Device Description

The *Excelsior SL-10 Microcatheter* is a single lumen device designed to aid the physician in accessing distal vasculature when used with a guide catheter and guidewire. The device shaft is comprised of graded materials of varying durometers, from a flexible tip to a semi-rigid proximal end. Stainless steel wire reinforcement provides for strength during torque transmission while the inner liner provides for lubricity. The hub / strain reliefs provide for kink resistance from the proximal end. A luer fitting on the catheter hub is used for the attachment of accessories. The radiopaque tip with one or two markers allows for visualization under fluoroscopy. The outer surface is coated with a hydrophilic coating which reduces friction during navigation in the vasculature. A steam shaping mandrel accessory is packaged with the catheter.

The *Excelsior SL-10 Microcatheter* will be manufactured in varying lengths. Model numbers and a device drawing are included in Section 4 of this submission.

h. Intended Use

The *Excelsior SL-10 Microcatheter's* Indications For Use are as follows:

Excelsior SL-10 Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.

The intended use of the modified device, as described in its labeling, has not changed as a result of the modifications.

i. Product Feature Comparison

Feature	Tracker-10 Microcatheter Predicate cleared under K925813	Excelsior SL-10 Microcatheter Subject device	Excelsior 1018 Microcatheter Predicate cleared under K994155
Intended Use	Tracker-10 Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.	Excelsior SL-10 Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.	Excelsior 1018 Microcatheter is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.
Design:			
Size (French)	2 French	1.7 French	2 French
Inside Diameter (ID)	0.015" minimum	0.016" minimum	0.0185" minimum
Outside Diameter (OD)	0.034"	0.031"	0.034"
Materials	Predominately polypropylene, polyethylene and polycarbonate	Predominately polyamide, stainless steel and rubber	Predominately polyamide, stainless steel and rubber

j. Comparison of Technological Characteristics

Excelsior SL-10 Microcatheter is substantially equivalent to Boston Scientific Target's Tracker-10 Microcatheter and Excelsior 1018 Microcatheter. *Excelsior SL-10 Microcatheter* is substantially equivalent to the predicate devices in terms of functionality, intended use, design, materials and method of operation.

k. Testing

In vitro performance testing of *Excelsior SL-10 Microcatheter* included dimensional inspection, tensile strength, burst pressure, flow rate and withdrawal force testing. All testing indicates that the device is safe and performs according to its intended use.

Biocompatibility testing was verified according to ISO-10993, *Biological Evaluation of Medical Devices*. Test results confirm biocompatibility of the *Excelsior SL-10 Microcatheter*.

l. Summary of Substantial Equivalence

Boston Scientific Target's determination of substantial equivalence to Tracker–10 Microcatheter and Excelsior 1018 Microcatheter predicate devices is based on the following.

The subject catheter is substantially equivalent to Tracker – 10 Microcatheter with respect to the following:

- size
- intended use
- labeling
- biocompatibility
- packaging
- sterilization methods

The subject catheter is substantially equivalent to Excelsior 1018 Microcatheter with respect to the following:

- materials
- intended use
- size
- labeling
- biocompatibility
- packaging
- sterilization methods

Based on the above information provided in this submission, Boston Scientific's *Excelsior SL-10 Microcatheter* is substantially equivalent to Boston Scientific's Excelsior 1018 Microcatheter and Tracker–10 Microcatheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Mr. George J. Prendergast
Regulatory Affairs Specialist II
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

Re: K013789
Excelsior™ SL-10 Microcatheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter.
Regulatory Class: Class II
Product Code: DQY
Dated: November 9, 2001
Received: November 14, 2001

Dear Mr. Prendergast:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific
TARGET

INDICATIONS FOR USE STATEMENT

510(k) Number: K013789

Device Name: *Excelsior SL-10 Microcatheter*

Indications for Use:

The *Excelsior SL-10 Microcatheter* is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013789