

AUG 3 2000

510(K) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Contact Person:

Linda Guthrie
Senior Regulatory Affairs Specialist
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

Device Name:

Excelsior™ 1018 Microcatheter, Class II

Device Description:

The *Excelsior 1018 Microcatheter* is a single lumen device designed to aid the physician in accessing the distal vasculature when used with a guiding catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over selectively placed guidewires without displacement of the wire. A luer fitting located on the catheter hub is used for the attachment of accessories. A radiopaque tip facilitates fluoroscopic visualization. The outer diameter is coated with a hydrophilic surface that reduces friction during manipulation in the vessel. The catheter is packaged with a steam shaping mandrel accessory.

Indications for Use:

Like the predicate *TurboTracker-18 Infusion Catheter* device, the *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.

Predicate Device:

TurboTracker®-18 Infusion Catheter K960806, cleared May 2, 1996

Testing in Support of Substantial Equivalence Determination

The *Excelsior 1018 Microcatheter* has different technological characteristics. However, the results of performance testing (tensile strength, coefficient of friction, static rupture, tip buckling, dimensional inspection, critical bend radius, particulate analysis, and coil compatibility) and biocompatibility testing support this claim of substantial equivalence. Results of the performance and biocompatibility testing, as presented in this pre-market notification, demonstrate that the *Excelsior 1018 Microcatheter* is substantially equivalent to the predicate *TurboTracker-18 Infusion Catheter* device. See Table 1 for a comparison of the technological characteristics.

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Section 2 - Table 1, Technological Characteristics Summary

Characteristic	*Predicate Device	<i>Excelsior 1018 Microcatheter</i>
Shaft Materials	Thermoplastic	Thermoplastic
Shaft Design	Metal reinforced	Metal reinforced
Distal Shaft Length	0 - 80 cm	6 cm
Proximal ID / OD	0.020" / 0.038"	0.0185" / 0.034"
Distal ID / OD	0.020" / 0.033"	0.0185" / 0.025"
Tip Markers	Platinum Iridium	Platinum Iridium
Coating	Hydrophilic Polymer	Hydrophilic Polymer
Effective Length	15 - 200 cm	105 cm - 150 cm
**GDC® Compatibility	GDC-18	GDC-10 & GDC-18

* *TurboTracker-18 Infusion Catheter* (K960806, May 1996)

**Boston Scientific Target's *Guglielmi Detachable Coils* (K962503, September 1996)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Roxanne K. Baxter
Manager, Regulatory Affairs
Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

Re: K994155
Trade Name: Excelsior 1018 Microcatheter
Regulatory Class: II
Product Code: KRA
Dated: May 4, 2000
Received: May 8, 2000

Dear Ms. Baxter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

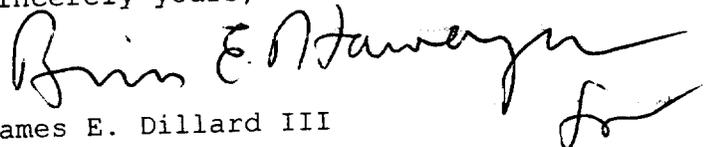
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Roxanne K. Baxter

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



INDICATIONS FOR USE STATEMENT

510(k) Number: K994155

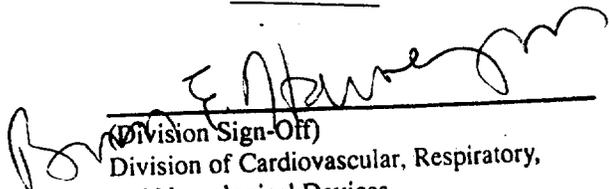
Device Name: *Excelsior™ 1018 Microcatheter Catheter*

Indications for Use: The *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.

(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 Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
Boston Scientific Target
510(k) Number Section 1, Page 2 of 8