

2/23/99

K98236J

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(j)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

A. GENERAL INFORMATION

Owner Operator Submitting Boston Scientific Corporation
this Premarket Notification: One Boston Scientific Place
Natick, MA 01757
(508) 650.9174
Contact Person: Wanda M. Carpinella
Regulatory Affairs Department
Device Generic Name: Thrombectomy Catheter
Device Classification: 74 DXE, Catheter Embolectomy

B. INDICATIONS FOR USE

The Oasis Thrombectomy System is a percutaneous, hydrodynamic, mechanical thrombectomy device designed for use with standard angiographic injectors. The catheter uses a high velocity saline stream to microfragment and remove thrombus from hemodialysis access grafts.

C. DESCRIPTIVE CHARACTERISTICS

The catheter features an outer shaft and is comprised of three: an inflow lumen to supply saline to the catheter tip, an outflow lumen for removal of thrombotic material and a guidewire lumen to accommodate an 0.018 inch guidewire. The catheter is 6F in diameter and is available in soft and braided configurations.

D. SUBSTANTIAL EQUIVALENCE

The subject thrombectomy catheter has been shown to be substantially equivalent to the Fogarty Embolectomy Balloon Catheter and Microvena's 8F Clot Buster Amplatz Thrombectomy Catheter. Results from a randomized, prospective clinical trial established that the proposed thrombectomy catheter is safe and effective for treatment of thrombosed hemodialysis grafts when compared to pulsed spray thrombolytic therapy.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

The catheter is packaged in a heat-sealed Tyvek/mylar pouch. The product is sterilized using ethylene oxide gas. Boston Scientific monitors bacterial endotoxins on product on a monthly basis.

F. CONCLUSION

Based on the information presented, Boston Scientific Corporation believes that the thrombectomy catheter meets the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently thrombectomy catheters.

000175



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 1999

Ms. Laura Mondano
Manager Regulatory Affairs
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K982363
Trade Name: Oasis™ Thrombectomy Catheter System
Regulatory Class: II
Product Code: MCW
Dated: November 23, 1998
Received: November 25, 1998

Dear Ms. Mondano:

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

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 the 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" (21 CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

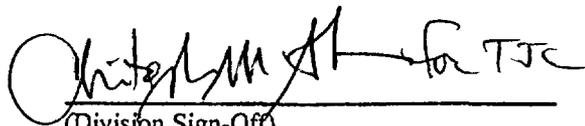
510(k) Number (if known): New Application

Device Name: Oasis™ Thrombectomy System

Indications for Use: The Oasis Thrombectomy System is a percutaneous, hydrodynamic, mechanical thrombectomy device designed for use with standard angiographic injectors. The catheter uses a high velocity saline stream to microfragment and remove thrombus from hemodialysis access grafts.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K982363

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)