FEB 12 1998

16. 510(k) Summary

Date Prepared June 30, 1997

Submitter

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Device Name and Classification

Trade Name: Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter

Common Name: Percutaneous Transluminal Angioplasty (PTA) Catheter

Classification: Class II

Predicate Device Match-35™ Percutaneous Transluminal Angioplasty (PTA) Catheter - K913297, K926271 and K942154

Device Description
The Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter consists of a bilumen catheter with a controlled-compliance balloon mounted at the distal tip. The balloon is designed to inflate to a known diameter and length at a specific pressure and is inflated and deflated via the side port. The second lumen allows access to the distal tip of the catheter for guidewire insertion, pressure monitoring and infusion of contrast media. Two marker bands are positioned under the balloon at the proximal and distal tapers to aid in accurate placement.

Intended Use
The Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter is recommended for use in percutaneous dilatation of the iliac, femoral, popliteal, tibial, renal, and tibioperoneal vessels in whose lumens are obstructed by atherosclerotic plaque. This catheter is not intended for use in the coronary arteries. Any other use than those indicated is not recommended.

Technical Characteristic Comparison to Predicate

The Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter has the same intended use and basic construction as the predicate device, the Match-35™ Percutaneous Transluminal Angioplasty (PTA) Catheter. The following table compares the technical characteristics of the two devices:

Feature	Match-35™ Percutaneous Transluminal Angioplasty (PTA) Catheter	Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter
Configuration	Bilumen	Bilumen
Shaft Length (cm)	40-200	60-120
Shaft French Size	5	5
Balloon Length (mm)	20-100	20-80
Balloon Diameter (mm)	3-12	3-12
Rated Burst Pressure (atm)	7-12	7-15
Guidewire Size (inches)	0.035	0.035
Balloon Markers	2 (Gold / Tantalum)	2 (Gold)
Balloon Material	Polyethylene Terephthalate	Nylon
Manifold Material	Polycarbonate	ABS
Shaft Material	Polyester	Nylon

Performance Data

The Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter had non-clinical performance testing as did the predicate device, the Match-35™ Percutaneous Transluminal Angioplasty (PTA) Catheter.

Testing of the Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter generally followed the PTCA Balloon Catheters section in Part II of the "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices", May 1994. The following types of tests were performed similar to those in the guidance:

Balloon Minimum Burst Strength
Balloon Compliance (Distensibility)
Balloon Inflation/Deflation Performance
Balloon Fatigue (Repeated Balloon Inflation)
Bond Strength
Catheter Diameter and Balloon Profile
Catheter Body Burst Pressure

The following additional evaluations were also performed by Schneider (USA):

Resistance through Stenosis
Pull Back Resistance into Introducer
Trackability
Catheter Prep Time

The biocompatibility of the catheter was also tested and found acceptable.

Summary
In summary, Schneider (USA) Inc has demonstrated the Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter is substantially equivalent to the Match-35™ Percutaneous Transluminal Angioplasty (PTA) Catheter based on design, test results, and indications for use and is therefore acceptable for commercialization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1998

Mr. Ronald W. Bennett
Senior Regulatory Affairs Specialist
Schneider (USA) Inc.
Pfizer Hospital Products Group
5905 Nathan Lane
Minneapolis, MN 55442

Re: K972512
Smash™ Percutaneous Transluminal Angioplasty (PTA)
Regulatory Class: II (two)
Product Code: 74 LIT
Dated: January 16, 1998
Received: January 20, 1998

Dear Mr. Bennett:

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 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.

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) 594-4648. 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/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):

Device Name: **Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter**

Indications for Use:

The Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter is recommended for use in percutaneous dilation of the iliac, femoral, popliteal, tibial, renal, and tibioperoneal vessels in whose lumens are obstructed by atherosclerotic plaque. This catheter is not intended for use in the coronary arteries. Any other use than those indicated is not recommended.

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 K972512

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

(Optional Format 1-2-96)