

AUG 9 2000

K993913

510 (k) SUMMARY

General Information

Classification	Class II
Trade Name	TRUE PTA Balloon Catheter
Submitter	Infinity Extrusion & Engineering, Inc. 3350 Scott Boulevard. Building 6 Santa Clara, CA. 95054 (408)727-6030 FDA Registration No.: 2951240
Contact	Douglas Wilkins Vice President

Intended Use

The TRUE PTA Balloon Catheter is intended for percutaneous dilatation of the iliac, femoral, popliteal, tibial, renal, infra popliteal, ilio femoral, and tibioperoceal arteries.

Predicate Devices

The Smash™ PTA Catheter from Schneider, Incorporated.

Device Description

The TRUE PTA Balloon Catheter is a non-reusable multiple lumen catheter with a balloon mounted on its distal tip. The TRUE PTA Balloon Catheter is packaged sterile and intended for single use only.

Materials

All materials used in the manufacture in the TRUE PTA Balloon Catheter are biocompatible and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specifications as well as substantial equivalence. Testing included balloon burst strength, balloon distensibility, balloon inflation/deflation, balloon fatigue, bond strengths, dimensional equivalence, shaft burst pressure, balloon preparation, tip pulling/torquing and biocompatibility.

Summary of Substantial Equivalence

The TRUE PTA Balloon Catheter is equivalent to the predicate Smash™ product from Schneider, Incorporated. The clinical indications for use, basic overall function, methods of manufacturing, and materials used are all substantially equivalent, Infinity Extrusion & Engineering believes that the TRUE PTA Balloon Catheter is substantially equivalent to existing marketing devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 9 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Douglas Wilkins
Vice President
Infinity Extrusion & Engineering, Inc.
3350 Scott Boulevard, Building 6
Santa Clara, CA 95054

Re: K993913
Trade Name: TRUE PTA Balloon Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: July 11, 2000
Received: July 12, 2000

Dear Mr. Wilkins:

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 (Pre-market 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 pre-market 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.

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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

510(k) Number (if known): K993913
This application

Device Name: TRUE PTA Balloon Catheter

Indications for Use: Intended for Percutaneous Dilatation of the iliac, femoral, popliteal, tibial, renal, infra popliteal, ilio femoral, and tibioperoneal arteries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K993913

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)