K012641

OCT 1 5 2001

510(k) Summary
FAS Endoluminal Brush

Submitter (Consultant) Name and Address

Morningstar Consulting Group, Inc.
P. O. Box 219
Indian Hills, CO 80454

Submitter (Consultant) Contact Person

Thomas Kroenke, Senior Consultant
phone (303) 956-4232
fax: (419) 858-9171

Manufacturer Name and Address

FAS Medical Limited
Unit E4, Brooklands Close
Sunbury, Middlesex TW16 7DX
United Kingdom

Manufacturer Contact Person

Laura Garcia, COO
Phone 44 1932 780333
Fax 44 1932 771488

Common Classification & Proprietary Names

Common Name:	Central Venous Catheter Biopsy Brush
Classification Name:	Intravascular Catheter, Accessory to
Proprietary Name:	FAS Endoluminal Brush

Predicate Devices

K993613	FAS Endoluminal Brush
K963925	Thrombolytic Brush Catheter
K993816	Fogarty Adherent Clot Catheter

Device Description

The FAS Endoluminal Brush is a single use, sterile disposable medical device. The device itself consists of nylon bristles wound into a stainless steel flexible wire, which is further wound into a stainless steel tubular handle. The brush is enclosed in a plastic sterile sheath that is heat sealed at the proximal end and is attached to a Luer lock at its distal end. The Luer lock attachment provides the brush access to catheter lumens in a sterile environment.

The FAS Endoluminal Brush kit also contains accessory items including a patient drape, instructions for use, wire clippers, and specimen container and cap, and a patient identification label.

Indications for Use

The FAS Endoluminal Brush is intended to collect and remove obstructing material from the internal lumen surface of an indwelling central venous catheter to restore or improve catheter flow rate, and to provide a biofilm or fibrin sample which is suitable for microbiological analysis.

Technological Characteristics Comparison

The FAS Endoluminal brush is an accessory to a central venous catheter. The purpose of the FAS Endoluminal Brush is to collect a biosample for subsequent microbiological analysis in much the same way as intended for a cytology brush and a microbiology brush, both described as predicates. Additionally, the FAS Endoluminal Brush removes obstructing material from the internal lumen surface of an indwelling central venous catheter and restores or improves catheter flow rate.

The FAS Endoluminal Brush and its predicates are constructed in a similar way, with brush bristles wound around the distal end of a flexible or rigid stainless steel wire.

Test Discussion

Testing was performed according to international standards to assure biocompatibility, sterility assurance, and general device safety.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally and by a third party conforms to the device performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2001

FAS Medical Limited
C/O Mr. Thomas Kroenke
Senior Consultant
Morningstar Consulting Group, Incorporated
P.O. Box 219
Indian Hills, Colorado 80454

Re: K012641
Trade/Device Name: FAS Endoluminal Brush
Regulation Number: 880.5970
Regulation Name: Accessory to, Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: August 10, 2001
Received: August 13, 2001

Dear Mr. Kroenke:

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.

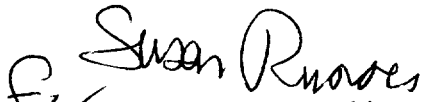
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012641

Device Name: FAS Endoluminal Brush

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(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)

(Optional Format 1-2-96)

Joan Nemeth for PKC

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012641