JAN 1 8 2000

K993614

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

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Manufacturer Name and Address

FAS Medical Limited
Unit E4, Brooklands Close
Sunbury-on-Thames, Middlesex
TW16 7DX England

Manufacturer Contact Person

Laura Garcia, COO
phone: 011 44 1932 780333
fax: 011 44 1932 771488

Common, Classification & Proprietary Names

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

Predicate Devices

Digene Cervical Brush (K971586)
Mill-Rose Microbiology Brush (K960880)

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 the catheter lumen in a sterile environment.

The FAS Endoluminal Brush kit also contains accessory items including a measuring tape, 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 a biofilm or fibrin sample, which is suitable for microbiological analysis, from the inner lumen surface of an in-dwelling central venous catheter.

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. 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 clinical safety of the device.

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

JAN 1 8 2000

Ms. Lynne Aronson
Senior Consultant
Morningstar Consulting Group, Inc.
Regulatory & QA Consultants
to the Medical Device Industry
PO Box 219
Indian Hills, Colorado 80454

Re: K993614
Trade Name: Fas Endoluminal Brush
Regulatory Class: Unclassified
Product Code: LJS
Dated: October 19, 1999
Received: October 25, 1999

Dear Ms. Aronson:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4692. 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,

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): K993614

Device Name: FAS Endoluminal Brush

Indications for Use:

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

(Optional Format 1-2-96)

Patricia Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993614