K033368

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XIV. 510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Fossa Medical, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." Fossa chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**Fossa Ureteral Open Lumen Stent**
510(k) Sponsor:	Fossa Medical, Inc. 580 Harrison Avenue, 4th Floor Boston, MA 02118
Device Generic Name:	Ureteral stent
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78FAD), and is classified under 21 CFR 876.4620.
Predicate Devices:	Fossa Ureteral Stone Sweeper (K031292) Fossa Double Pigtail Expanding Ureteral Stent (K021140)

Product Description:
The Fossa Ureteral Open Lumen Stent set consists of a flexible, pigtail-tipped stent with: "Pusher," and optional pre-attached suture to facilitate stent removal. The stent is offered in various diameters and working lengths. The stent has two lumens open to the outside of the stent.

Indications for Use:
The Fossa Ureteral Stone Sweeper is indicated for use as an indwelling ureteral catheter to promote drainage of urine from the kidney to the bladder.

Safety and Performance:
This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), Fossa Medical has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Performance testing conducted in support of this submission includes dimensional inspection, elongation/yield and tensile strength testing, guidewire passage evaluation, compression strength and flow rate analysis.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the Fossa Ureteral Open Lumen Stent has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Ms. Gloria Kolb
President
Fossa Medical, Inc.
580 Harrison Avenue, 4th Floor
BOSTON MA 02118

Re: K033368
Trade/Device Name: Fossa Ureteral Open Lumen Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: 78 EYB
Dated: October 20, 2003
Received: October 29, 2003

Dear Ms. Kolb:

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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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" (21CFR Part 807.97) you may obtain. 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) PREMARKET NOTIFICATION

510(k) Number (if known): _____

Device Name: Ureteral Open Lumen Stent

Indications for Use:

The Fossa Ureteral Open Lumen Stent is indicated for use as an indwelling ureteral catheter to promote drainage of urine from the kidney to the bladder.

(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 Reproductive, Abdominal, and Radiological Devices
510(k) Number K033368

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)