XII. 510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, Fossa Industries, 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 Stone Sweeper**
510(k) Sponsor:	Fossa Industries, Inc. 580 Harrison Avenue, 4th Floor Boston, MA 02118
Device Generic Name:	Ureteral stent / retrieval basket
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78FAD / 78FGO), and is classified under 21 CFR 876.4620 / 21 CFR 876.4680).
Predicate Devices:	Cook Double Pigtail Polyurethane Stent Bard Double Pigtail Ureteral Stent Surgitek Stone Basket Boston Scientific (Van-Tec) Segura Basket

Product Description:
The Fossa Ureteral Stone Sweeper set consists of a flexible, Pigtail tipped, self-expanding stent with: Insertion sheath, "Pusher," and optional pre-attached suture to facilitate stent removal. The stent is offered in various diameters and working lengths. Short slits along the working length of the stent allow radial device expansion to permit fluid flow through and around the device, and to permit stone passage into the inner stent's lumen.

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, and/or for the manipulation, capture and removal of urinary calculi.

Safety and Performance:
Product performance testing has been provided in support of this 510(k) in accordance with FDA's *Guidance for the Content of Premarket Notifications for Ureteral Stents* and *510(k) Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastorenterology and Urology.* The materials used in the construction of the Fossa stent are identical to those used in other currently marketed urinary drainage and stone removal devices.

Conclusion:
Based on the indications for use, technological characteristics, performance testing and comparison to predicate devices, the Fossa Ureteral Stone Sweeper 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

JUL 2 6 2002

Fossa Industries, Inc.
c/o Pamela Papineau, RAC
Consultant to Fossa Industries, Inc.
Delphi Medical Device Consulting
5 Whitcomb Avenue
AYER MA 01432

Re: K021602
Trade/Device Name: Fossa Ureteral Stone Sweeper
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Product Code: 78 FAD
Regulation Number: 21 CFR 876.4680
Regulation Name: Ureteral stone dislodger
Product Code: 78 FGO
Regulatory Class: II
Dated: May 9, 2002
Received: May 15, 2002

Dear Ms. Papineau:

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 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 this 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" (21 CFR 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,

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): K021602

Device Name: Ureteral Stone Sweeper

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, and/or for the manipulation, capture and removal of urinary calculi.

(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)

David A. Lagman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021602