AUG 1 1 1998

K982464

P192

WOMEN FIRST HEALTHCARE

510(k) SUMMARY

SUBMITTER'S NAME:	Women First HealthCare, Inc.
ADDRESS:	12220 El Camino Real, Suite 400 San Diego, California 92130
TELEPHONE:	(619) 509-1171
FAX:	(619) 509-1353
CONTACT PERSON:	Jeanne-Marie Varga Vice President Regulatory Affairs and Quality Systems
DATE PREPARED:	July 13, 1998
NAME OF DEVICE:	
Proprietary Name:	SCC-23 Safety Clamp and Cutter
Common/Usual Name:	Umbilical clamp and cutter
Classification Name:	Umbilical Clamp Umbilical Scissors Ob/Gyn Specialized Manual Instruments
PRODUCT CODE:	85 HFW, HDJ, & KNA
CLASS:	II
CLASSIFICATION REGULATIONS:	21 CFR 884.4530

K982464
1 of 2

WOMEN FIRST
HEALTHCARE

PREDICATE DEVICE: Veridien Corporation's umbilical clamping shear, K963428

DESCRIPTION OF DEVICE: The SCC-23 Safety Clamp and Cutter is a pre-sterilized, ready-to-use, disposable obstetric instrument comprising a piston housing and two clamps manufactured of Polyamid 6.6 (nylon) which, upon incineration, converts to water vapor. The product also incorporates a stainless steel blade protectively sealed within the piston. The entire device weighs approximately 0.8 ounces or 23 grams. The clamp weighs approximately 0.1 ounces or 2.8 grams.

INTENDED USE: The SCC-23 Safety Clamp and Cutter is intended to simultaneously cut and clamp the umbilical cord following birth. The device reduces the risk to healthcare practitioners of unnecessary exposure to infection by bloodborne diseases.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS: Both the SCC-23 Safety Clamp and Cutter and the Veridien Corporation umbilical clamping shear comprise two clamps and a cutter designed to simultaneously clamp and cut the umbilical cord.

SUBSTANTIAL EQUIVALENCE: The SCC-23 Safety Clamp and Cutter is substantially equivalent to the umbilical clamping shear from Veridien Corporation, St. Petersburg, Florida, K963428.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 1998

Ms. Jeanne-Marie Varga
Vice.President
Regulatory Affairs and Quality Systems
WOMEN FIRST Health Care
12220 El Camino Real
Suite 400
San Diego, CA 92130

Re: K982464
SCC-23 Safety Clamp and Cutter
Dated: July 13, 1998
Received: July 15, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 KNA

Dear Ms. Varga:

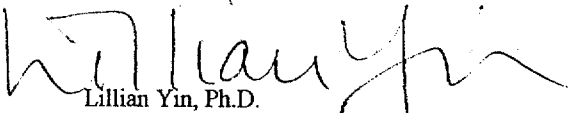
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

***510(k) Number* (if known):** K982464

***Device Name*: SCC-23 Safety Clamp and Cutter**

***Indications for Use*:**

The indications for use of the SCC-23 Safety Clamp and Cutter are to simultaneously clamp and cut the umbilical cord. The device reduces the risk to healthcare practitioners of unnecessary exposure to infection by bloodborne diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Cathey
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Diseases

510(k) Number K982464

Prescription Use X or Over-the-Counter Use_____

(Optional Format 1-2-96)