K021876

510(k) Summary
As Required by 21 section 807.92 (c)

APR 0 8 2003

1-Submitter Name: Mansour Consulting LLC
2-Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
3-Phone: (678) 908- 8180
4-Fax: (425) 795- 9341
5-Contact Person: Jay Mansour
6-Date summary prepared: May 28th, 2002
7-Device Trade or Proprietary Name: Marina Ampler Sampler (with and without syringe)
8-Device Common or usual name: Endometrial Suction Curette
9-Device Classification Name: Curette, Suction, Endometrial
10-Substantial Equivalency is claimed against the following device:

- Curelle from Bioteque Corporation, 510k #K915491

11-Description of the Device:

The ETO sterilized **MAS** w/ Syringe is used to obtain a sample of differential endometrial tissue. The **MAS** w/ syringe is a 3mm (O.D.) endometrial suction device that has a Randall-like cutting edge at its distal end and is packaged with a twist-and-lock syringe. The syringe will provide a vacuum or suction during the procedure. The **MAS** w/ syringe is sterile unless the package is opened or damaged and designed for single patient use only.

The ETO sterilized **MAS** without syringe is used to obtain a sample of differential endometrial tissue. The **MAS** is a [redacted], 3 or 3.5mm (O.D.) endometrial suction curette that has a fenestration on the wall at its distal end and a tight fitting piston that will provide a vacuum or suction during the procedure as it is pulled proximally. The **MAS** is sterile unless the package is opened or damaged and designed for single patient use only.

12-Intended use of the device:

This device is indicated for use to remove material from the uterus and from the mucosal lining of the uterus by scraping and vacuum suction in order to obtain tissue for histological biopsy or for menstrual extraction

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

FDA file reference number	510k 915491	
Attachments inside notification submission file	Appendix 1 and 2	
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**	
	With Syringe	**Without Syringe**
Indications for use	Identical	
Target population	Identical	
Design	Identical	Similar
Materials	Identical	
Performance	Identical	
Sterility	Identical (Ethylene Oxide)	
Biocompatibility	Identical	
Mechanical safety	Identical	
Chemical safety	Identical	
Anatomical sites	Identical	
Human factors	Identical	
Energy used and/or delivered	Identical	
Compatibility with environment and other devices	Identical	Similar
Where used	Identical	
Standards met	Identical	
Electrical safety	Identical (not applicable)	
Thermal safety	Identical (not applicable)	
Radiation safety	Identical (not applicable)	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 8 2003

Marina Medical Instruments, Inc.
% Mr. Jay Mansour
Regulatory Consultant
Mansour Consulting, LLC
1308 Morningside Park Dr.
ALPHARETTA GA 30022

Re: K021876
Trade/Device Name: MAS With or Without Syringe
Regulation Number: 21 CFR 884.1175
Regulation Name: Endometrial suction curette and accessories
Regulatory Class: II
Product Code: 85 HHK
Dated: January 28, 2003
Received: January 30, 2003

Dear Mr. Mansour:

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) Number (if known): K021876

Device Name: MAS WITH SYRINGE & WITHOUT SYRINGE

Indications For Use:

THE DEVICE IS INDICATED FOR USE TO REMOVE MATERIAL FROM THE UTERUS AND FROM THE MUCOSAL LINING of THE UTERUS BY SCRAPING AND VACUUM SUCTION IN ORDER TO OBTAIN TISSUE FOR HISTOLOGICAL BIOPSY OR FOR MENSTRUAL EXTRACTION.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Krysmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021876

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

(Optional Format 1-2-96)