K974032

P1/3

DEC 22 1997

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

1-Submitter Name: A & A Medical, Inc.
2-Address: 4100 Nine McFarland Drive, suite B
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jihad Mansour
6-Date summary prepared: October 22nd, 1997
7-Device Trade or Proprietary Name: Mucus Sampler Syringe
8-Device Common or usual name: Mucus Sampler Syringe
9-Device Classification Name: Endocervical Aspirator
10-Substantial Equivalency is claimed against the following devices:

1-AspiretteEndocervical Aspirator from *Unimar, Inc.*
2-SelectMucus from *Select Medical Systems, Inc*
3-Cervical Mucous Aspiration Catheter from *Cook Urological, Inc*

11-Description of the Device:

The Rocket Mucus Sampler is designed for optimum suction for the collection of cervical mucosal lining, post coital test (Huhner), external os or vaginal pool sampling. It is comprised of 3 components: Plunger, O-ring and external tubing. Suction is created by pulling the plunger with a handle outward.
It has a small OD of 2.6mm, which minimizes pain and discomfort to the patient. The Rocket Mucous Sampler enables the Ob/Gyn physician to collect the specimen and send it to the laboratory to be examined histologically or cytologically

12-Intended use of the device: (ALSO PRINTED SEPARATELY ON FDA FORM)

The Rocket Mucus Sampler is designed for optimum suction for the collection of cervical mucosal lining, post coital test (Huhner), external os or vaginal pool sampling. The Rocket Mucous Sampler enables the Ob/Gyn physician to collect the specimen and send it to the laboratory to be examined histologically or cytologically

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13-Safety and Effectiveness of the device:

Rocket Mucus Sampler Syringe is as safe and effective as other predicate devices cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate devices:

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

P.S. *Abbreviations used below: E=Equivalent, S=Similar, D=Different, N/A= Not Applicable, DES=Description available, N/I=No Information available, 510(k) Sum=510(k)Summary available, 510(k)=510(k) available, web=fda web printout enclosed*

			TECHNOLOGICAL CHARACTERISTICS															
	FDA file reference number	Attachments inside Notification	Indications for use	Target population	Design	Materials	Performance	Sterility	Biocompatibility	Mechanical Safety	Chemical Safety	Anatomical sites	Human Factors	Energy used and/or delivered	Compatibility w/ environment & other devices	Where used	Standards met	Electrical Safety
1- Aspirette Endocervical Aspirator from Unimar, Inc.	k895403	web 510k	E	E	S	S	E	S	S	N/A	E	S	N/A		E	E	N/A	
2- SelectMucus from Select Medical Systems, Inc.	k954102	web 510k	E	E	S	S	E	S	S	N/A	E	S	N/A		E	E	N/A	
3- Cervical Mucous Aspiration Catheter from Cook Urological, Inc.	k960263	web 510k & summary	E	E	S	S	E	S	S	N/A	E	S	N/A		E	E	N/A	

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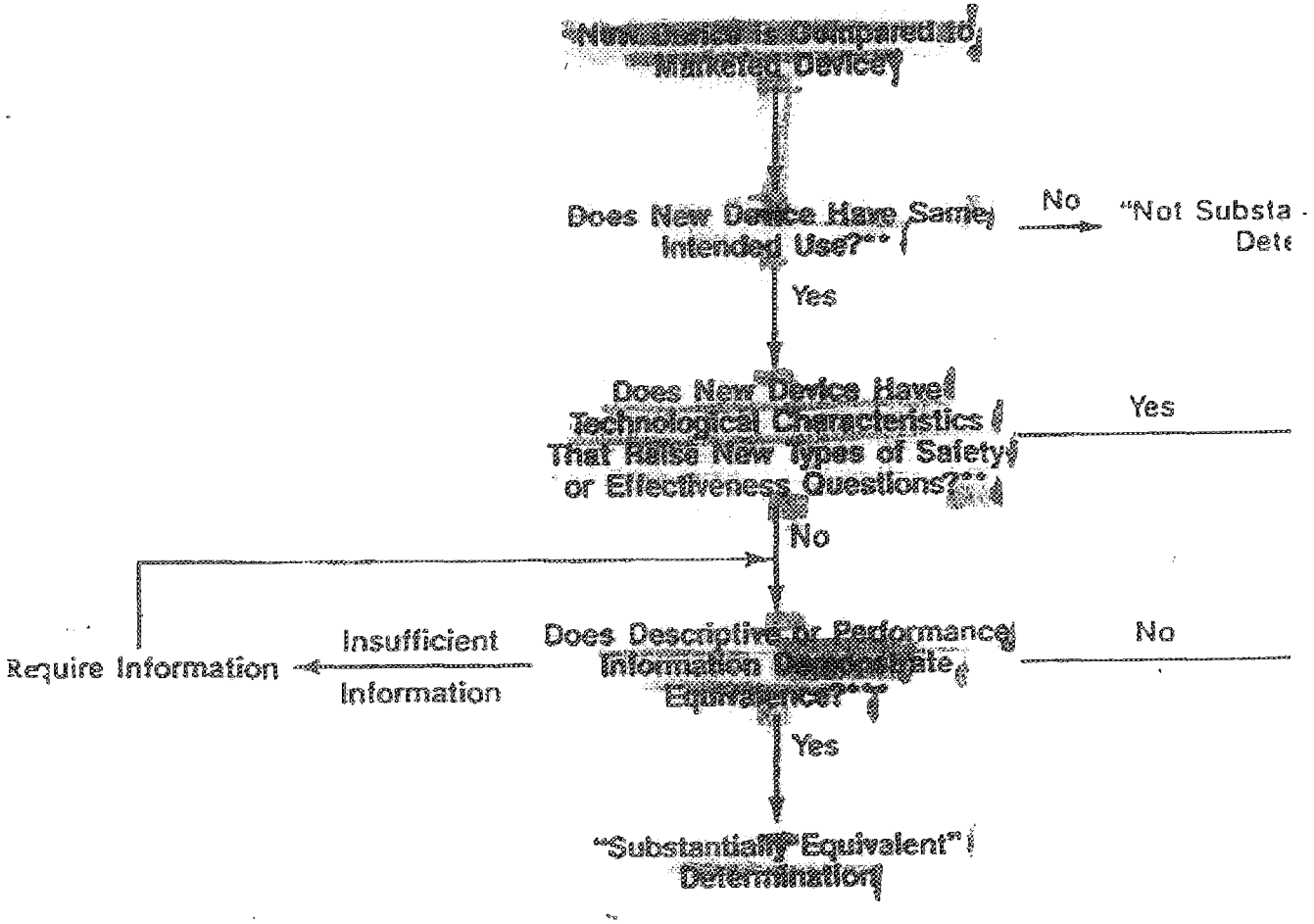
510(k) "Substantial Equivalence" Decision-Making Process (Overview)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Infor if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Device is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Informa is Sometimes Required.

*** Data May Be In the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

A more Detailed version is also available in pdf version or found directly below.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1997

Mr. Jihad Mansour
Quality Assurance & Regulatory Affairs Manager
A & A Medical, Inc.
Nine McFarland Drive, Suite B
Alpharetta, Georgia 30004-3386

Re: K974032
Rocket Mucus Sampler Syringe
Dated: October 22, 1997
Received: October 23, 1997
Regulatory class: II
21 CFR §884.1050/Product code: 85 HFC

Dear Mr. Mansour:

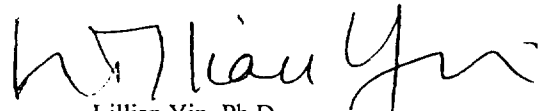
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

510(k) Number (if known): K974032

Device Name: Rocket Mucus Sampler Syringe

Indications For Use:

The Rocket Mucus Sampler is designed for optimum suction for the collection of cervical mucosal lining, post coital test (Huhner), external os or vaginal pool sampling.
The Rocket Mucous Sampler enables the Ob/Gyn physician to collect the specimen and send it to the laboratory to be examined histologically or cytologically

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974032

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

(Optional Format 1-2-96)