K013437

NOV 1 9 2001

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: A & A Medical, Inc.
2-Address: 9370 Industrial Trace
Alpharetta, GA 30004
3-Phone: (770) 343- 8400
4-Fax: (770) 343- 8985
5-Contact Person: Jay Mansour
6-Date summary prepared: October 8th, 2001
7-Device Trade or Proprietary Name: 5F SH Catheter
8-Device Common or usual name: Catheter for Sonohysterography
9-Device Classification Name: Cannula, Manipulator/Injector, Uterine
10-Substantial Equivalency is claimed against the following device:

- Ultra Catheter Set for Sonohysterography, from Lyco Enterprises, Inc.

11-Description of the Device:

The device is to be used by physicians in hospitals

The 5F SH catheter consists of two parts: a single lumen catheter and a semi-rigid introducing sheath.

The catheter is available in a 5 French diameter with a length of 32 cm. The distal end has a side port. The proximal end is fitted with a female luer-lock hub. The catheter is banded with a non-toxic ink 7 cm from the distal tip

The semi-rigid sheath has an internal diameter to allow movement over the catheter and a wall thickness sufficient to provide semi-rigid flexibility. The sheath is 17.5 cm long and flanged and rounded at the distal end to provide a non-traumatic surface to the tissues. The proximal end allows for temporary fixation over the proximal hub of the catheter.

12-Intended use of the device:

The 5F SH Catheter is a device used to fill the uterus with sterile saline to facilitate the ultrasound examination of the uterus

13-Safety and Effectiveness of the device:

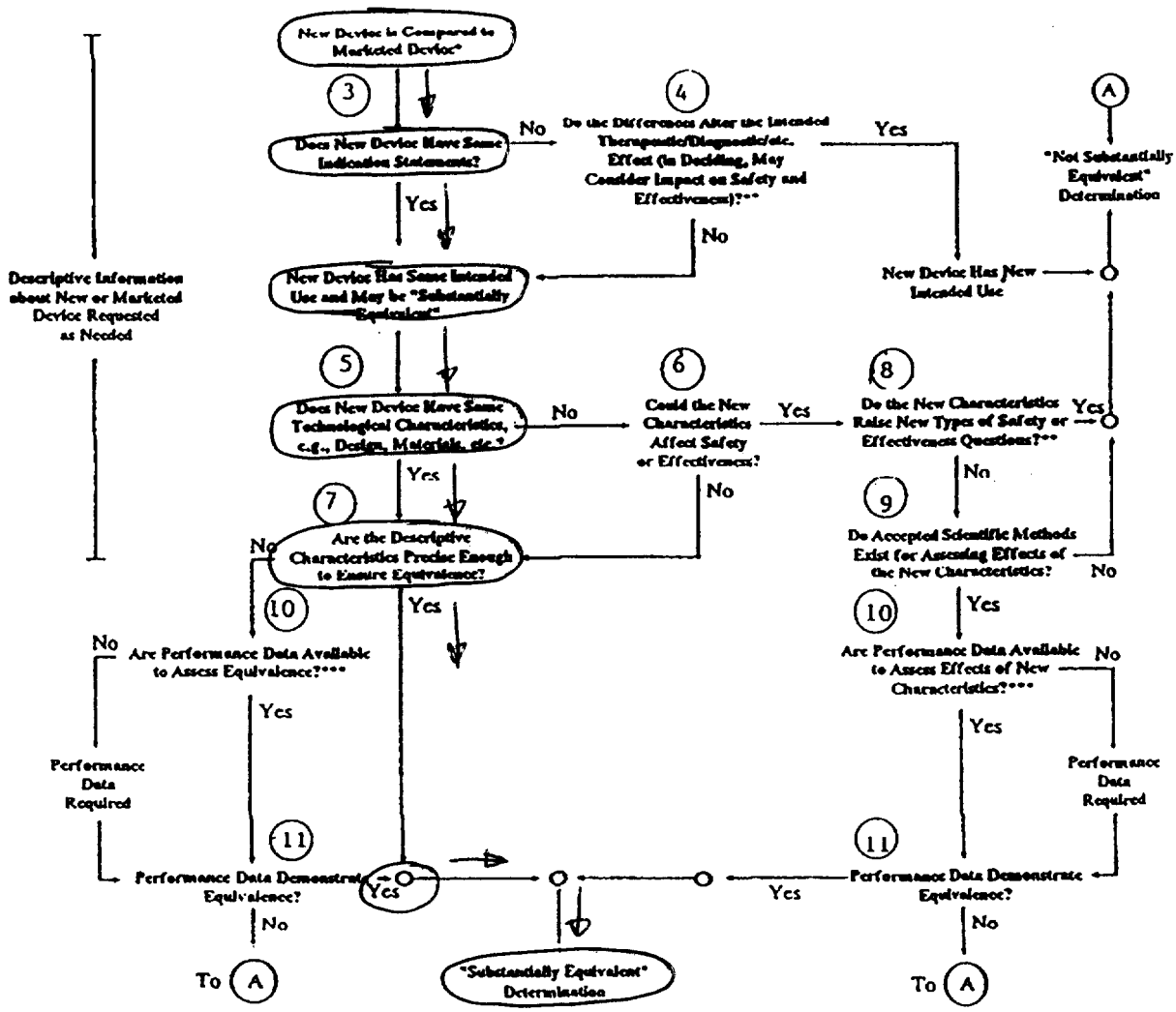
This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

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 K001115
Attachments inside notification submission file	REFER TO TABLE ON PAGE 11 OF 12 FOR DETAILS
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Similar (Ethylene Oxide instead of Gamma)
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
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2001

Jay Mansour, MSQA, BE, LA, RAC
Quality and Regulatory Manager
A&A Medical, Inc.
9370 Industrial Trace
ALPHARETTA GA 30004

Re: K013437
Trade/Device Name: Sonohysterography Catheter, Model R65-946
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 85 LKF
Dated: October 8, 2001
Received: October 17, 2001

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.

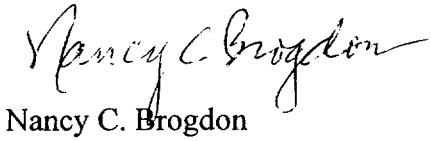
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 1 9 2001

510(k) Number (if known): K013437

Device Name: SONOHYSTEROGRAPHY CATHETER (5 Fr) [R65-946]

Indications For Use:

THE SONOHYSTEROGRAPHY CATHETER (5 Fr) IS INDICATED FOR USE TO FILL THE UTERUS WITH STERILE SALINE TO FACILITATE THE ULTRASOUND EXAMINATION OF THE UTERUS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013437

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

(Optional Format 1-2-96)