K 972245

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: Adib Khoury
6-Date summary prepared: June 9th, 1997
7-Device Trade or Proprietary Name: TomCat
8-Device Common or usual name: IUI catheter
9-Device Classification Name: Intrauterine insemination cannula
10-Substantial Equivalency is claimed against the following devices:

1-Makler Insemination Device from *Sefi-Medical Instruments*
2-CSI Insemination Instrument and Sheath from *Rocket of London*
3-Oligospermis Cup from *The Milex Products Inc*
4-Cervical Cap from *The Lamberts (Deleton) Limited*
5-Seminor from *Promedex Inc*
6-Uni-Sem (TM) from *Unimar Inc*
7-Jansen-Anderson Insemination Set from *Cook Ob/Gyn*
8-Lifetek IUI Catheter from *Lifetek Medical Inc*
9-Insemi-Cath from *Cook Ob/Gyn*
10-Select IUI from *Select Medical Systems Inc*
11-Insemi-cath II from *Cook Ob/Gyn*
12-Genxcatheter from *Gnx Intl. Inc*
13-Wallace Artificial Insemination catheter- 8CM/18C M from *Marlow Surgical Technologies Inc*
14-Intrauterine Insemination Catheter from *Conceptus Inc*
15-Insemi-Cath Insemination catheter from *Cook Ob/ Gyn*
16-Edwards-Wallace Bourne-Hall from *Marlow Surgical*
17-Intrauterine Insemination and Sonohysterography catheter from *Ackrad Laboratories*
18-Resubmitted Artificial Insemination Instrument set from *Laboratoire ccd c/o Washington Regulatory Service*
19-Shepard Intrauterine Insemination catheter from *Cook Ob/Gyn*
20-Minispace (TM) IUI Catheter from *Pharmacia Inc*

11-Description of the Device:

The TomCat IUI catheter is a 3 ½ french catheter with a length of 5 ½ ". This catheter expands in size in the proximal area to accommodate a syringe tip. It is made out of propylene of class VI Grade.

12-Intended use of the device:

The TomCat allows the sperm to bypass the cervix so that an increased number can reach the Uterine cavity and subsequently the fallopian tubes, which may increase the pregnancy rate in couples with unexplained infertility

13-Safety and Effectiveness of the device:

TomCat is 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 TomCat 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, N/A= Not Applicable, DES=Description available, N/I=No Information available, 510(k) Sum=510(k)Summary available, 510(k)=510(k) available*

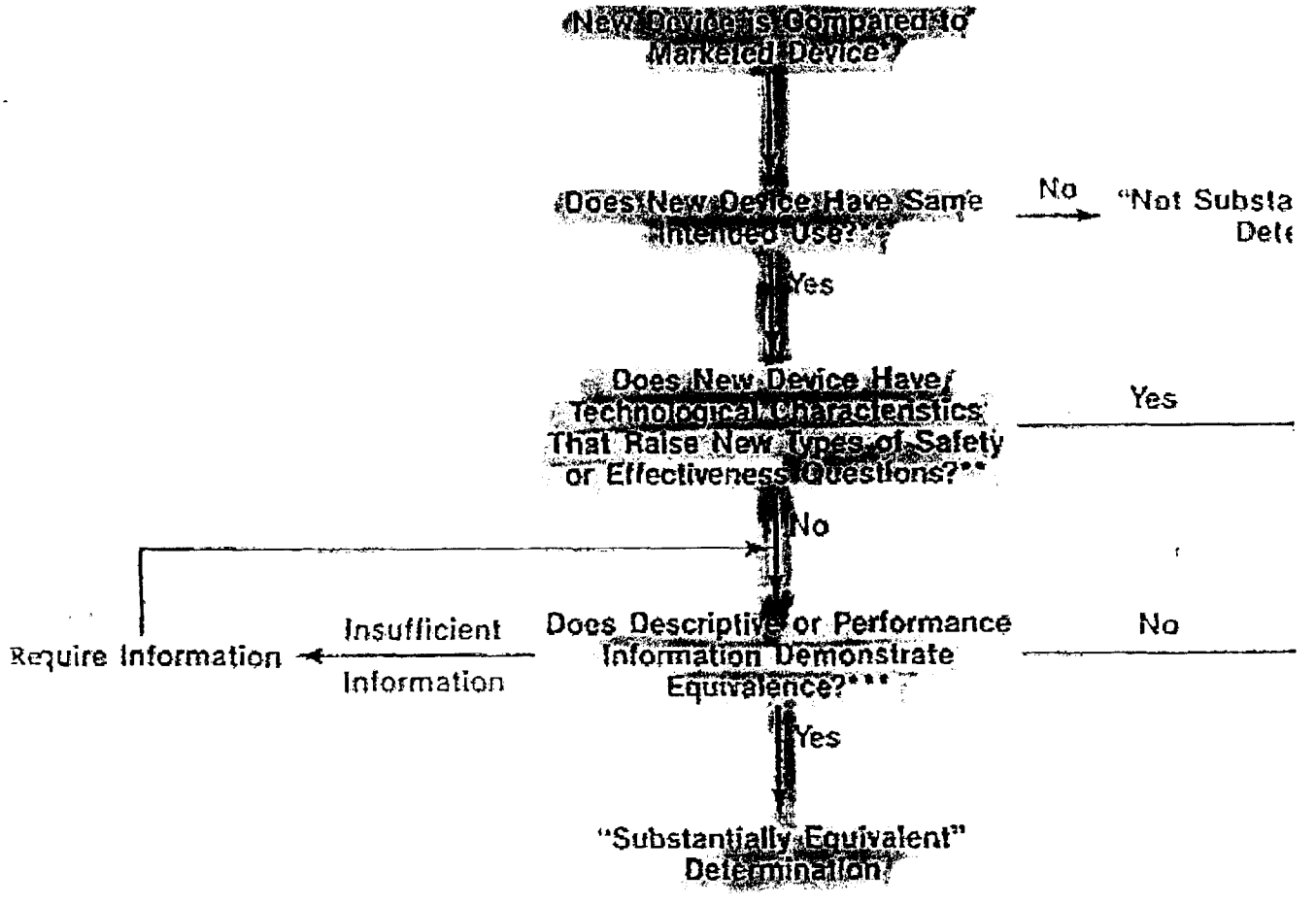
			TECHNOLOGICAL CHARACTERISTICS																		
	FDA file reference number	ATTACHMENTS INSIDE NOTIFICATION	Indications for use	Target population	Design	Materials	Performance	Sterility	Biocompatibility	Mechanical Safety	Chemical safety	Anatomical sites	Human factors	Energy used and/or delivered	Compatibility w/ environment & other devices	Where used	Standards met	Electrical safety	Thermal Safety	Radiation safety
1-Sefi-Medical Instruments **Makler Insemination Device**	N/I	DES &AD COPY	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
2-The Rocket of London **CSI Insemination Instrument and Sheath**	N/I	DES	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
3-The Milex Products, Inc. **Oligospermis Cup**	N/I	DES	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
4-The Lamberts (Deleton) Limited **Cervical Cap**	N/I	DES	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
5-Promedex, Inc **SEMINOR**	k905764	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
6-Unimar, Inc. **UNI-SEM(TM)**	k910317	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
7-Cook Ob/Gyn **JANSEN-ANDERSON INSEMINATION SET**	k914150	510K	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
8-Lifetek Medical,Inc. **LIFETEK IUI CATHETER**	k921518	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A

Table- Cont'd

9-Cook Ob/Gyn **INSEMI-CATH**	k870551	510k	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
10-Select Medical systems, Inc **SELECT IUI**	k954099	510k sum	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
11-Cook Ob/Gyn **INSEMI-CATH II**	k954398	510k sum	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
12-Gnx Intl. ,Inc **GENXCATHETER**	k963031	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
13-Marlow Surgical Technologies, Inc **WALLACE ARTIFICIAL INSEMINATION CATHETER- 8CM/18C**	k964848	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
14-Conceptus, Inc. **INTRAUTERINE INSEMINATION CATHETER**	k932993	510k sum	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
15-Cook Ob/Gyn **INSEMI-CATH INSEMINATION CATHETER**	k931630	510k	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
16-Marlow Surgical **EDWARDS-WALLACE BOURNE-HALL**	k910577	510k	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
17-Ackrad Laboratories **INTRAUTERINE INSEMINATION AND SONOHYSTERO-GRAPHY CATHETER**	k970492	N/I	S	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
18-Laboratoire ccd c/o Washington Regulatory Service **RESUBMITTED ARTIFICIAL INSEMINATION INSTRU-MENT SET**	k884695	N/I	E	E	E	E	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
19-Cook Ob/Gyn **SHEPARD INTRA-UTERINE INSEMINATION CATHETER**	k890301	N/I	E	E	S	S	E	S	S	N/A	N/A	E	E	N/A	S	E	E	N/A	N/A	N/A
20-Pharmacia, Inc. **MINISPACE(TM) IUI CATHETER**	k902171	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I	N/I

ATTACHMENT 1

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

AUG - 6 1997

Mr. Adib Khoury
President
A & A Medical, Inc.
4100 Nine McFarland Drive, Suite B
Alpharetta, Georgia 30004

Re: K972245
TomCat Intrauterine Insemination Catheter
Dated: June 11, 1997
Received: June 16, 1997
Regulatory class: unclassified
Product code: 85 MFD

Dear Mr. Khoury:

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) K972245

Device Name: ~~TOMCAT INTRAUTERINE~~ INSEMINATION CATHETER

Indications For Use:

The TomCat Intrauterine Insemination Catheter allows the sperm to bypass the cervix so that an increased number can reach the Uterine cavity and subsequently the fallopian tubes.

This catheter can handle washed sperm to be delivered into the uterine cavity.

This device is not intended for assisted reproduction procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972245

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

(Optional Format 1-2-96)