

OCT 10 1997

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## 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:** July 28th, 1997  
**7-Device Trade or Proprietary Name:** Mini-Embryon Intra Uterine  
Insemination Catheter  
**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-Seminor from Promedex Inc*  
*2-Lifetek IUI Catheter from Lifetek Medical Inc*  
*3-Select IUI from Select Medical Systems Inc*  
*4-Intrauterine Insemination Catheter from Conceptus Inc*  
*5-Edwards-Wallace Bourne-Hall from Marlow Surgical*  
*6-Resubmitted Artificial Insemination Instrument set from Laboratoire ccd c/o  
Washington Regulatory Service*

#### 11-Description of the Device:

The Mini Embryon IUI is a 5Fr Intrauterine Inseminator made of clear polyethylene, 18 cm in length, with an OD of 1.6 mm and an ID of 1.0 mm. A 5 cm distal segment with double side eyes and a rounded tip insures a very smooth entry with minimal disturbance to the endometrial bed. This is complemented with 11 cm of marked catheter shaft with 7 Fr in diameter for better and more secure handling. A proximal Luer Lock allows for connection with a syringe. It is to be supplied in two versions, Soft & Hard.

#### 12-Intended use of the device:

The Mini Embryon 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

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**13-Safety and Effectiveness of the device:**

Mini Embryon 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 Mini Embryon 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

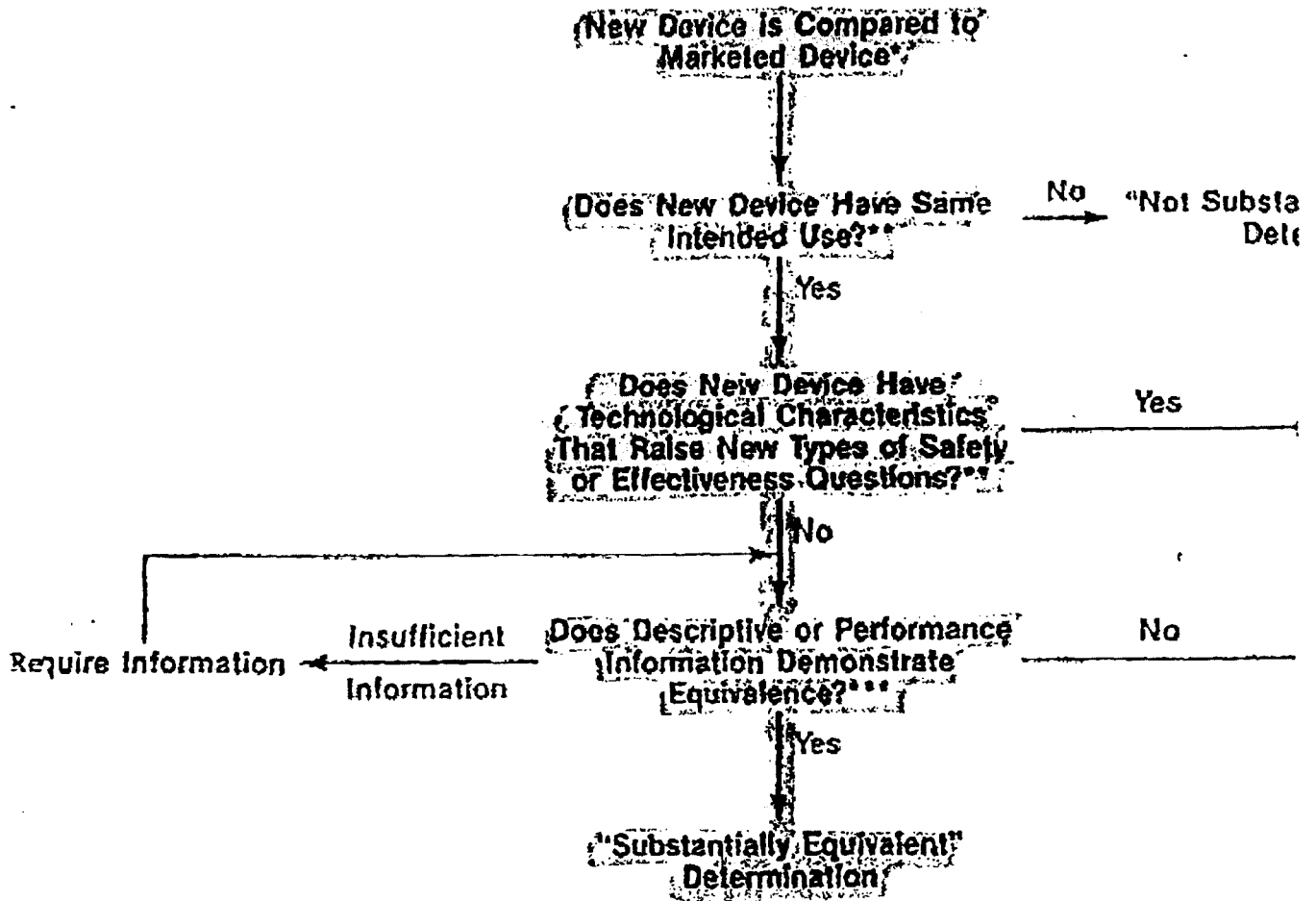
	FDA file reference number	ATTACHMENTS INSIDE NOTIFICATION	Indications for use	Target population	Design	Materials	Performance	Sterility	Biocompatibility	Mechanical Safety	Chemical safety	Anatomical sites	Human factors	Energy used and/or delivered	Compatibility w/ environment & other devices	Where used	Standards met	Electrical safety	Thermal Safety	Radiation safety
1-Promedex, Inc <b>SEMINOR</b>	K305764	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
2-Lifetek Medical, Inc. <b>LIFETEK IUI CATHETER</b>	K921516	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
3-Select Medical systems, Inc <b>SELECT IUI</b>	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
4-Conceptus, Inc. <b>INTRAUTERINE INSEMINATION CATHETER</b>	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
5-Marlow Surgical <b>EDWARDS-WALLACE BOURNE-HALL</b>	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
6-Laboratoire ccd c/o Washington Regulatory Service <b>RESUBMITTED ARTIFICIAL INSEMINATION INSTRUMENT SET</b>	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

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ATTACHMENT I

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



- \* 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) Device 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.

A more Detailed version is also available in [pdf version](#) or found directly below.

End of Summary



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OCT 10 1997

Mr. Adib Khoury  
President  
A&A Medical, Inc.  
4100 Nine McFarland Drive, Suite B  
Alpharetta, Georgia 30004-3386

Re: K972823  
Mini-Embryon Intrauterine Insemination Catheter  
Dated: September 3, 1997  
Received: September 4, 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

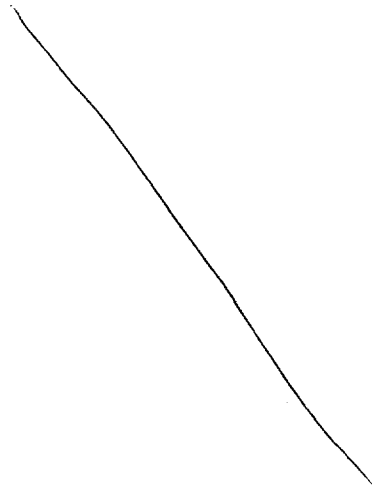
510(k) Number (if known): K972823

Device Name: MINI EMBRYON INTRAUTERINE INSEMINATION CATHETER

Indications For Use:

The Mini Embryon 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 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)

Robert R. Nathan /  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K972823

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format I-2-96)