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K973671

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

NOV 26 1997

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
6-Contact Person: Jihad Mansour
6-Date summary prepared: September 24th , 1997
7-Device Trade or Proprietary Name: Endocervical Block Needle
8-Device Common or usual name: Hypodermic Needle
9-Device Classification Name: Hypodermic Single Lumen Needle
10-Substantial Equivalency is claimed against the following device:

Potocky needle™ Disposable Injection Needle from Coopersurgical

11-Description of the Device:

The needle is 27g, 3 ½" long. It is used for uterine anesthesia prior to Ob/Gyn procedures. It consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (Luer lock) designed to mate with a male connector (Nozzle) of a piston syringe or an intravascular administration set. Over 3 ¼" of its proximal end a 21 gauge metal tube is added to strengthen the shaft

12-Intended use of the device: *(Indications for use typed on a separate FDA form)*

This needle is designed for injection of solutions (such as 2% lidocaine with or without 1:100,000 epinephrine) into the cervix. Local anesthetics such as electroexcision, electrofulguration, CO2 laser excision and vaporization, and in some patients, endocervical curettage and cervical biopsies

13-Safety and effectiveness of the device:

The **Endocervical Block Needle** is safe and effective as the Potocky Needle ™. Indeed, it is equivalent
This is better expressed in the tabulated comparison (Paragraph 14 below)

PTO-→

14-Summary comparing technological characteristics with other predicate device:

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P.S. GENERAL COMPARISON RESULT BETWEEN **Potocky Needle ™** and **Endocervical Block Needle** is found tabulated below. Comparison of specific elements will be attached in the main submission as per FDA guidance for 510(k) Notifications for Hypodermic Single Lumen Needles

2-Target Population	Equivalent
3-Design	Equivalent
4-Materials	Equivalent
5-Performance	Equivalent
6-Sterility	Equivalent
7-Biocompatibility	Equivalent
8-Mechanical Safety	Equivalent
9-Chemical Safety	Not Applicable
10-Anatomical Sites	Equivalent
11-Human Factors	Equivalent
12-Energy used and/or delivered	Not Applicable
13-Compatibility with Environment & other devices	Equivalent
14-Where used	Equivalent
15-Standards met	Equivalent
16-Electrical Safety	Not Applicable
17-Thermal Safety	Not Applicable
18-Radiation Safety	Not Applicable

ATTACHMENT 1

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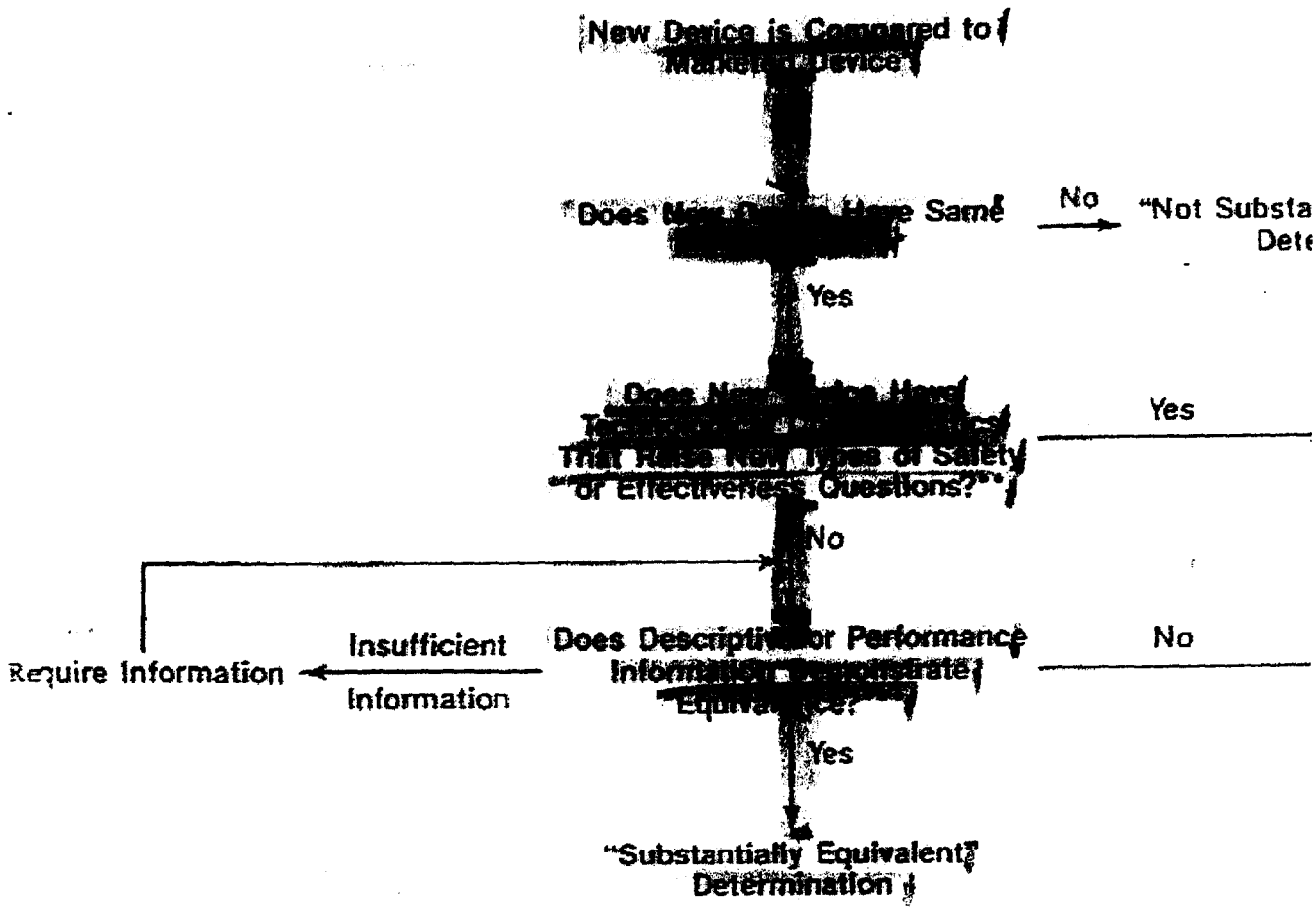
510(k) "Substantial Equivalence" Decision-Making Process (Overview)



* 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jihad Mansour
QA/RA Manager
A & A Medical, Inc.
4100 Nine McFarland Drive, Suite B
Alpharetta, Georgia 30004

Re: K973671
Endocervical Block Needle
Dated: September 24, 1997
Received: September 26, 1997
Regulatory Class: II
21 CFR §884.5100/Product Code: 85 HEE
21 CFR §880.5570/Product Code: 80 FMI

NOV 26 1997

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,

William Yin

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): K973671

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Device Name: Endocervical Block Needle

Indications For Use:

This needle is designed for injection of solutions (such as 2% lidocaine with or without 1:100,000 epinephrine) into the cervix. Local anesthetics such as electroexcision, electrofulguration, CO2 laser excision and vaporization, and in some patients, endocervical curettage and cervical biopsies

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973671

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)