

Section 6.0 510(k) Summary

K974389
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FEB 19 1998

510(k) Summary

Submitter: Clinical Innovations, Inc.
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Proprietary Names: Koala Intrauterine Pressure Catheter and
Koala External Intrauterine Pressure Catheter
Common/Usual Name: Intrauterine Pressure Monitor and Accessories
Classification Name: Monitor, Pressure, Intrauterine

The legally marketed devices to which equivalence is claimed are the Medex MX 4041 Intrauterine Pressure Catheter, Graphic Controls Life Trace 3000 Intrauterine Pressure Catheter System, and Utah Medical Products Intran Plus IUP Catheter.

Description of the device: An intrauterine pressure catheter with a pressure-sensing membrane cavity at the tip (either inside the catheter or mounted externally), a port for amniotinfusion and amniotic fluid sampling, and an introducer which is removed after placement. This product is a sterile, single patient use catheter. The system includes a reusable cable with a reusable pressure transducer.

Intended use: This catheter is for use on patients requiring intrapartum, intrauterine pressure monitoring.

The Koala IPC's are substantially equivalent to the predicate devices because: they have the same intended uses, namely, intrauterine pressure measurement and monitoring and amniotic fluid access, and

- they have the same basic technological characteristics as predicate devices, namely, pressure sensor located at catheter tip,
- soft tip for low risk of perforation,
- markings for catheter insertion,
- low-cost disposable in order to avoid cross contamination,
- port and lumen with female luer connector for access to amniotic space, and
- external zeroing of pressure.

They use the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application.

The safety and effectiveness are similar to existing devices as demonstrated in the laboratory and in clinical testing. Biocompatibility testing shows that the materials used

in the Koala IPC and the Koala External IPC are safe for this application. Effectiveness is the same as the predicate devices. The laboratory testing verified the performance in terms of sensor accuracy, mechanical integrity, and overall performance.

Wm. Dean Wallace
Wm. Dean Wallace, M.D., Ph.D.

11-18-97
Date

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Wm. Dean Wallace, M.D., Ph.D.
President
Clinical Innovations
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Murray, UT 84107

Re: K974389
Koala Intrauterine Pressure Catheters,
Models 5000 and 5000E
Dated: November 19, 1997
Received: November 21, 1997
Regulatory Class: II
21 CFR 884.2700/Procode: 85 HFN

Dear Dr. Wallace:

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

