Section 6.0 510(k) Summary

K973746

P191

510(k) Summary

NOV 24 1997

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

The legally marketed devices to which equivalence is claimed are the pre-filled syringes used with the Medex MX 4042 Series Intrauterine Pressure Catheter and the Quest (formerly Healthdyne Cardiovascular) ISOFLO Intrauterine Pressure Monitoring & Amnio.

Description of the device: The pre-filled Syringe is 10 cc syringe filled with 0.9% isotonic saline and is an accessory to the Koala Intrauterine Pressure System used in priming the catheter. This product is a sterile, single-use device.

Intended use: This accessory is used with a Koala Intrauterine Pressure System and is used in priming the catheter.

The pre-filled syringe is substantially equivalent to the predicate device because:

- It has the same intended uses, namely, to prime the catheter in intrauterine pressure monitoring,
- It has the same basic technological characteristics as predicate devices, namely, it is a syringe pre-filled with saline, and
- It uses 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. Biocompatibility testing shows that the materials used in the pre-filled syringe are safe for this application. Effectiveness is the same as the predicate devices.

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

10-6-97
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 24 1997

Wm. Dean Wallace, M.D., Ph.D.
President
Clinical Innovations
6477 S. Cottonwood Street
Murray, Utah 84107

Re: K973746
Pre-filled Syringe for Koala Intrauterine Pressure Catheter
Dated: September 29, 1997
Received: October 1, 1997
Regulatory class: II
21 CFR §884.2700/Product code: 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,

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

11.0 Indications For Use

Device Name: Pre-filled Syringe for Koala Intrauterine Pressure Catheter

510(k) Number: K973746

Intended use: This accessory is used with a Koala Intrauterine Pressure System and is used in priming the catheter.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Watkins /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973746

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

(Optional Format 1-2-96)