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510 (k) SUMMARY

JUN - 6 1997

I. ADMINISTRATIVE

Submitter: MK Conquest International, Inc.
4201 N. Main Street, Suite 220-G
Fort Worth, Texas 76106

Contact Person: Eric Kudimi
(817) 625-6565

Date Prepared: March 21, 1997

II. DEVICE NAME

Proprietary Name: Anokryo

Common Name: Rectal Dilator

Regulatory Class: Class I

Product Code: 78FFP

III. PREDICATE DEVICES

Commercially available rectal dilators such as the Anurex (K862490) and the Inamed Rhemo-D (K894618).

IV. DEVICE DESCRIPTION

The Anokryo Dilator consists of a narrow tapered shaft approximately 2.75 inch long and 0.5 inch wide. The hollow interior of the shaft is filled with hydroxyethylcellulose solution before the shaft is molded to a flange knob which serves as a handle The shaft and flange are composed of polyethylene.

The device is supplied clean and non-sterile in a plastic storage container and a water-soluble lubricant gel. Prior to use, the rod is stored in its container for 1-2 hours and then moistened with the lubricant gel. A maximum low temperature of -15° C is obtained and sustained for 10 minutes. The device is easily cleaned with detergent and water and stored in its container for reuse.

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V. INTENDED USE

Dilation of the anal sphincter and canal for the relief of hemorrhoidal pain and itching, reduction of bleeding, and promotion of healing of inflamed hemorrhoidal tissues.

VI. COMPARISON TO PREDICATE DEVICES

The Anokryo Dilator is similar in design and identical in function and intended use to legally marketed rectal dilators such as the Anurex and Inamed Rhemo-D devices.

Accordingly, MK Conquest International, Inc. has concluded that the Anokryo Dilator is safe and effective for its intended use and performs at least as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Eric Kudimi
President
MK Conquest International, Inc.
Fort Worth Meacham Airport
Terminal Building
4201 N. Main Street, Suite 220-G
Fort Worth, Texas 76106-2747

JUN - 6 1997

Re: K964634
Anokryo Rectal Dilator
Dated: March 21, 1997
Received: March 24, 1997
Regulatory class: I
21 CFR §876.5450/Product codes: 78 FFP and LKX

Dear Mr. Kudimi:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

Robert K Watkins

for 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): K964634

Device Name: Anokryo

Indications for Use:

- Dilation of the anal sphincter and canal for the relief of hemorrhoidal pain and itching, reduction of bleeding, and promotion of healing of inflamed hemorrhoidal tissues.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert B Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964634

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

(Optional Format 1-2-96)