K971275

510(k) Summary:

1.) Submitter: Mill-Rose Laboratories, Inc.
7310 Corporate Blvd.
Mentor, OH 44060
(216)255-7995

MAY 23 1997

2). Contact Person: Alan C. Poje

3.) Summary Preparation Date:
April 4, 1997

4.) Classification Name: Snare, Flexible (Accessory to Endoscopic Electrosurgical Unit)

5.) Common Name: Disposable Polypectomy Snare

6.) Proprietary Name: Mill-Rose Disposable Polypectomy Snare

7.) Substantially Equivalent Device:

K912254 - Cox Medical Enterprises, Cox Disposable Polypectomy Snare

K792343 - Mill-Rose Laboratories, Flexible Diathermic Snare

K951600 - Mill-Rose Laboratories, Rotatable Polypectomy Snare

8.) Description of Subject Device:

The device consists of a handle, cable, snare loop and cable. The loop is attached to the handle assembly by means of the cable. The sheath is also connected to the handle assembly and collapses the loop upon its retraction into the sheath.

9.) Intended Use:

The intended use of the subject device is to electrosurgically remove GI tract polyps through the channel of an endoscope

10.) Technological Characteristics:

The subject device has the same technological characteristics as the predicates. It is composed of the same type of materials and is of a similar design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 1997

Mr. Alan C. Poje
Director of Regulatory Affairs
Mill-Rose Laboratories, Inc.
7310 Corporate Boulevard
Mentor, Ohio 44060-4885

Re: K971275
Mill-Rose Disposable Polypectomy Snare
Dated: April 4, 1997
Received: April 7, 1997
Regulatory class: II
21 CFR §876.4300/Product code: 78 FDI

Dear Mr. Poje:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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,

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): K971275

Device Name: Mill-Rose Disposable Polypectomy Snare

Indications for Use:

The intended use of this device is to electro surgically remove GI tract polyps through the channel of an endoscope.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert J Calling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971275

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

(Optional Format 1-2-96)