OCT 30 1998

K983124

Attachment 4

510(k) Summary

Premarket Notification [510(k)]:

TBNA Cytology Procedural Kit

1. **Submitter:** Mill-Rose Laboratories, Inc.
7310 Corporate Blvd.
Mentor, OH 44060
(440) 255-7995
Contact: Alan C. Poje, Director of Regulatory Affairs and Quality

This summary was prepared on August 24, 1998.

2. **Proprietary Name:** Mill-Rose Laboratories Transbronchial Needle Aspiration (TBNA) Cytology Procedural Kit
Common Name: none
Classification Name: none

3. **Statement of Equivalence**

All the components of the kit are either legally marketed preamendments devices, exempt from premarket notification, or have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is to be intended. The following chart lists the components, their 510(k) status, and classification.

Components	510(k) Status	Classification
"MRL transbronchial aspiration needle (TBAN) of choice"	K914181	21 C.F.R. § 874.4680 Bronchoscope (flexible or rigid) and accessories, Class II
MW-100 lockable syringe (20cc)	K852607	21 C.F.R. § 880.5860 Piston syringe, Class II
95% EtOH fixative (50cc)	Exempt from premarket notification	21 C.F.R. § 864.4010 General purpose reagent, Class I

Components	510(k) Status	Classification
Cytolyt preservative (30cc vial)	Exempt from premarket notification	21 C.F.R. § 864.4010 General purpose reagent, Class I
NaCl irrigation solution (110cc)	Exempt from premarket notification	21 C.F.R. § 864.4010 General purpose reagent, Class I
Microscope slides (1" x 3")	Exempt from premarket notification	21 C.F.R. § 864.3010 Tissue processing equipment, Class I

4. Device Description

The Transbronchial Needle Aspiration Cytology Procedural Kit contains items for obtaining and handling of cytologic specimens in the context of a transbronchial aspirating needle procedure.

5. Intended Use

The Transbronchial Needle Aspiration Cytology Procedural Kit is intended to retrieve and handle specimens and to prepare them for proper cytopathic examination.

6. Technological Characteristics

The technological characteristics of the kit components do not vary from those of the components when used individually and not in the context of the kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 30 1998

Alan C. Poje
Director of Regulatory Affairs and Quality
Mill-Rose Laboratories, Inc.
7310 Corporate Blvd.
Mentor, OH 44060

Re: K983124
Mill-Rose Laboratories Transbronchial Needle
Aspiration (TBNA) Cytology Procedural Kit
Regulatory class: II/21 CFR 874.4680
Product Code: 77 EOQ
Dated: September 4, 1998
Received: September 8, 1998

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 to legally marketed predicate 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

for

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Health
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment 2

Indications for Use Statement

Premarket Notification [510(k)]:

TBNA Cytology Procedural Kit

Indications for Use:

The Transbronchial Needle Aspiration Cytology Procedural Kit is intended to retrieve and handle specimens and to prepare them for proper cytopathic examination.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983124