Canadian Medical Brush Inc.
2299 Drew Road, unit # 6 Mississauga, Ontario L5S 1A3 Canada

APR 16 1998

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510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Submitter:
Canadian Medical Brush Inc.
2299 Drew road, Unit #6
Mississauga, Ontario L5S 1A3
Canada
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Contact Person:
Stephen Jemuovic, Director, Regulatory Affairs
Canadian Medical Brush Inc
Phone: (905) 405- 1323
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Name of Device and Name / Address of Sponsor

Name of Device:
Cervical Cytology C-Brush

Sponsor:
Canadian Medical Brush Inc.
2299 Drew Road, Unit #6
Mississauga, Ontario L5S 1A3
Canada

Common or Usual Name:

Specimen (cervical) collection brush

Classification Name:

Spatula, cervical, cytological

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Predicate Device:

Team Technologies, Inc. - Cytology Brush (K971849)

Device Description:

The Cervical Cytology C-Brush has a truncated cone-shaped brush head composed of nylon bristles joined to a wire shaft. The brush head on the wire shaft is bonded to a plastic handle. To collect cervical cells, the brush end of the Cervical Cytology C-Brush is inserted 1.0 to 1.5 cm into the cervical os until the longest outer bristles of the brush touch the ectocervix. The brush is rotated two full turns in counter - clockwise direction and withdrawn.The brush is then used to spread the specimen onto a glass slide for a Pap smear.

Intended Use:

The Cervical Cytology C-Brush is intended for the collection of cervical cells for Pap smear analysis and /or for sexually transmitted disease (STD) testing. The Cervical Cytology C-Brush is not intended for use in pregnant women.

Technological Characteristics and Substantial Equivalence

The Cervical Cytology C-Brush is substantially equivalent in terms of Intended use, design, materials, manufacturing processes, physical properties, and principles of operation to the Team Technologies, Inc. Cytology Brush.

Phone: (905) 405-1075 Fax: (905) 405-1108 E-mail: cbrush@globalserve.net

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

Mr. Stephen Jemuovic
Director
Canadian Medical Brush, Inc.
2299 Drew Road, unit # 6
Mississauga, Ontario L5S 1A3
CANADA

Re: K980356
Cytology Cervical C-Brush
Dated: March 23, 1998
Received: March 31, 1998
Regulatory Class: II
21 CFR 884.4530/Procode: 85 HHT

Dear Mr. Jemuovic:

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 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, 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/dsma/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): K980356

Device Name: Cervical Cytology C-Brush

Indications For Use:

Indication for use are the endocervical collection of specimens used in Pap smear, chlamydia and HPV testing.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980356

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

(Optional Format 1-2-96)