DEC 2 1998

K981171

XI. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS, March 12, 1998 [Separate Pages]

I. Andre de Villers, Theratechnologies Inc., 630 Boul. Rene-Levesque Ouest, 5e étage, Montreal H3B 1S6, Quebec, Canada. Phone: 514-877-0077.

II. Classification Names and numbers: Dental Operative unit, accessory 76EIA.

III. Common/Usual Name: Accessory to dental unit, dental line-cleaner.

IV. Proprietary Names: Eradic-All™

V. Establishment Registration Number: In process

VI. Classification: Dental operative unit and accessories, Class I, reserved, Described in CFR 872.6640.

VII. Substantial Equivalence: Eradic-All™ is substantially equivalent to the classified device and those cleared for marketing by the 510(k) process under K-971278 (Pure Company, K-963548 (MRLB Int'l.) and K-930144 (SciTech Dental) and K-882491 (Micryllum Labs.)

The "510(k) Substantial Equivalence" Decision Making Process (Detailed) from ODE Guidance Memorandum # 36-3 was followed as described below:

1. These products have the same intended use to provide a cleaner water supply for use with dental operative units, including devices cleared for marketing by K-963548 and K-882491, K-930144 and K-971278.

2. The technological characteristics for this product are similar to those for the predicate devices and those currently on the market except for differences in methods of use. The technological features of the chemical solution used, although distinct, have the same intended use of reducing contaminants. The methods used with these equivalent products also vary widely including daily or weekly change, overnight soak or elution of traces of bactericide and filtering or non-filtering.

3. Descriptive information provided shows that the materials from which the delivery unit of Eradic-All™ is made are substantially equivalent to (identical with those of K-971278) those of similar products, used for identical purposes, currently on the market.

4. This product does not contact patients. Operating instructions clearly indicate the necessity for adequate flushing so the cleaning solution is removed from the water lines. Products from which the cleaning agent are prepared are accepted in food processing applications.

We have not been able to locate specific guidance documents applying to biofilm removal from dental lines. However, we believe we have complied fully with general guidance documents and usual practices in preparing premarket notifications. If additional information or explanation is needed, please call me at 514-877-0077 or fax me at 514-877-3177. Alternately, you may contact Dr. H. N. Dunning at 301-229-2138, 8309 Bryant Dr., Bethesda, MD 20817, who is acting on my behalf, for a local response.

Sincerely yours

Andre de Villers
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1998

Mr. Andre de Villers
Theratechnologies, Incorporated
630, boul.René-Lévesque Quest
5e étage
Montréal (Québec)
H3B 1S6

Re: K981171
Trade Name: Eradic-All
Regulatory Class: I
Product Code: EIA
Dated: October 20, 1998
Received: October 22, 1998

Dear Mr. de Villers:

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 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. 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) 594-4692. 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" (21CFR 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): NA K981171

Device Name: Eradic-All™

Indications For Use:

To isolate water delivery lines in the dental operatory unit and reduce the contamination due to biofilm to improve the quality of water supplied to dental handpieces and other dental instruments.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Browne for S. Runner

(Division Sign-Off)
Division of Dental, Infection
and General Hospital
510(k) Number K981171

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-9