DEC 21 1998

K983413

510(k) SUMMARY

Submitter:	Parkell Products Inc. 155 Schmitt Blvd. Box 376 Farmingdale, NY 11735 TEL: 516-249-1134 FAX: 516-249-1242
Contact:	Nelson J. Gendusa, DDS Director of Research Parkell 155 Schmitt Blvd. Box 376 Farmingdale, NY 11735
Submission Date:	September 24, 1998
Trade Name:	MODEL MS-1 HANDPIECE
Common Name:	Low-Speed Prophy Handpiece
Classification Name:	Dental Handpiece (C.F.R. §872.4200)
Equivalence:	Tri-Auto ZX, Periotest, Prophy Champ Handpiece, Robin Cordless Handpiece, M-3 Torx Handpiece and Yoshida Rido-F, Model LM-01.
Description/Intended Use:	The MODEL MS-1 HANDPIECE is an electrically-powered, low-speed handpiece intended for use with a contra-angle in which a rubber cup or bristle brush is inserted for the purpose of cleaning and/or polishing teeth using an appropriate prophylaxis paste, pumice/water mixture, or the like.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1998

Nelson J. Gendusa, D.D.S.
Parkell Products, Incorporated
155 Schmitt Boulevard
Box 376
Farmingdale, New York 11735

Re: K983413
Trade Name: Model MS-1 HANDPIECE
Regulatory Class: I
Product Code: EKX
Dated: September 24, 1998
Received: September 28, 1998

Dear Dr. Gendusa:

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): K983413

Device Name: MODEL MS-1 HANDPIECE

Indications for Use: An electrically-powered, low-speed (<5000 RPM) dental handpiece as defined in C.F.R. 872.4200 intended for use with a disposable contra-angle device which contains a suitable rubber cup, or similar for the purpose of cleaning and/or polishing teeth with an appropriate mixture of pumice and water, prophylaxis paste, or the like.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983413