K972376

SEP 10 1997

510(K) SUMMARY

I. Submitter:

Palisades Dental
A Division of Glenwood, L.L.C.
82 N. Summit Street
Tenafly, NJ 07670
Contact Person: Cynthia Romanoff
Telephone: (800) 664-8000

II. Date 510(k) Summary Prepared: June 20, 1997

III. Trade Name: Impact Air 45 Handpiece for Periodontal Use

IV. Classification Name: Dental Handpiece (21 C.F.R. §872.4200)

V. Predicate Devices: "Fiber Optic High Speed Handpiece" (K760794) and "Tradition High Speed Handpiece" (K863677), both manufactured by Midwest; the "Dental Handpiece" (K780038) by Lares Manufacturing Co.; and the "W-H Topair Dental Handpiece" (K912786) by Sabra.

VI. Device Description: The Impact Air 45 Handpiece for Periodontal Use is an air-powered dental handpiece intended for use in osteoplasty (bony contouring), odontoplasty, root resection, and other periodontal procedures for which a conventional handpiece would be used. The handpiece is intended to provide a better work environment than a conventional high-speed, air-powered handpiece in that (1) it is designed so that air is not directed onto the area of the bur and (2) it is designed with a 45-degree back-angled head shank to facilitate access.

The device is intended for use with all friction-grip burs, including surgical length burs, that conform to I.S.O. and A.D.A. shank diameter standards (0.0626 to 0.0630 inches). The recommended operating air pressure is between 32 and 40 pounds per square inch ("psi"), which results in high-speed bur rotation (approximately 400,000 to 500,000 revolutions per minute ("rpm")). The device includes a water line that directs water onto the spinning bur, which forms a cooling mist and also helps irrigate the working area. The use of sterile water is recommended. One model of the device also includes a fiberoptic bundle that directs light onto the working area.

The device may be connected to a standard compressed air source found in virtually all dental units. The use of filtered air is recommended. The air supply enters the device

through a tube in the handle and turns the turbine, which is in the head of the device, thus spinning the bur. The air exits the device principally through an air exhaust tube in the handle. A smaller portion of the air exits through the top of the head of the device. Virtually no air exits from the front of the head into the area of the bur.

The Impact Air 45 can be sterilized by autoclave when processed for 35 minutes at 250 degrees. Data indicate that after 250 sterilization cycles the handpiece continues to function appropriately.

VII. Substantial Equivalence: The Impact Air 45 is substantially equivalent to a number of conventional high-speed, air-powered dental handpieces including the "Fiber Optic High Speed Handpiece" (K760794) and "Tradition High Speed Handpiece" (K863677), both manufactured by Midwest; the "Dental Handpiece" (K780038) by Lares Manufacturing Co.; and the "W-H Topair Dental Handpiece" (K912786) by Sabra. Based on our familiarity with these devices, we have concluded that the Impact Air 45 has the same intended use, does not raise different questions of safety and effectiveness, and is fundamentally similar in operating principle, design, materials, energy source, and other characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1997

Mr. John I. Gruen
Member
Glenwood, L.L.C.
Palisades Dental
82 North Summit Street
Tenafly, New Jersey 07670

Re: K972376
Trade Name: Impact Air 45 Handpiece for Periodontal Use
Regulatory Class: I
Product Code: EFB
Dated: June 20, 1997
Received: June 25, 1997

Dear Mr. Gruen:

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 requirement, 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) 594-4618. 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,

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

Enclosure

Statement of Indications for Use

Device Name: Impact Air 45 Handpiece for Periodontal Use

Indications: The Impact Air 45 Handpiece for Periodontal Use is an air-powered dental handpiece intended for use in osteoplasty (bony contouring), odontoplasty, root resection, and other periodontal procedures for which a conventional handpiece would be used.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982376

Prescription Use ✓
(Per 21 CFR 801.109)