NOV 18 1998

K983163

ORA INNOVATIONS™

510(k) SUMMARY

CONFIDENTIAL

Contact person: Gerald L. Cogan

Date summary prepared: September 8, 1998

Device name:

Proprietary name: Avant™ High Speed Handpiece
Common or usual name: High speed dental handpiece
Classification name: Dental handpiece and accessories, Class 1, 21 CFR 872.4200

Legally marketed device for substantial equivalence comparison:

Midwest Tradition P High Speed Handpiece (K963050)
Manufactured by Dentsply Midwest, Des Plaines, IL

Description of the device:

The Avant is a high speed dental handpiece, 132 millimeters long, with a lightly textured finish for enhanced grip. It is a hand-held, channeled instrument that is powered by compressed air that is delivered through a hose to an air channel in the handpiece at 32-40 psi. This impels the turbine in the head of the handpiece to revolve at approximately 375,000 rpm. Other internal channels deliver air and water to the head for cleaning and cooling. The handpiece may contain, as an accessory, an optics device to light the area of operation. Any common dental bur for cutting (not supplied by Ora Innovations) is held in place in the handpiece head by a push-button chuck.

The Avant handpiece housing is constructed of a high temperature, medical grade liquid crystal polymer (Vectra® A530 by Ticona, Summit, NJ). There are three major parts which are made from metal: a standard turbine (supplied by a manufacturer of dental handpiece turbines), the threaded connector at the back end which attaches to the standard air/water hose in the dental unit, and the internal tubes that carry the chip air and water. These three parts are substantially equivalent to those in the predicate device.

Similar to the predicate device, the Avant handpiece must be cleaned and lubricated with a quality commercial dental handpiece cleaner/lubricant. It is supplied non-sterile, but must be sterilized before use, as with the predicate device. It will be packaged as a single unit or in multiples.

Ora Innovations, Inc.

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Portland, Oregon USA 97209

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Intended use of device:

The Avant handpiece will be used by dentists to remove decayed tooth structure, and to cut or alter the shape of teeth so they may be restored to form and function.

The following tests were derived from the American Dental Association guideline, ISO 7785-1 and G95-1/ISO-10993:

- Air pressure
- Biocompatibility
  - Polymer material
  - Color
- Extraction force
- Rotational speed
- Sterility validation

The test reports, located in the Appendix of the 510(k) application, show that the Avant handpiece is safe and effective.

The Avant handpiece is similar to the predicate device in that they both perform the same functions in the same manner, directing air at high pressure to metal turbines which rotate dental cutting burs. Both devices have tubes which direct air and water to the head to clean and cool the area, and they both can be steam sterilized. In addition, they have the option of including an optical light feature.

The principal difference lies in the construction of the housing of the handpieces. The Avant head and handle are made from a high temperature, medical grade polymer that will retain dimensional stability and strength through multiple sterilization cycles. The head and handle of the predicate device are made of stainless steel.

Performance testing: Comparative performance testing and clinical evaluations are not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1998

Gerald L. Cogan, DMD
Director of Clinical Affairs
Ora Innovations, Incorporated
319 S.W. Washington Street, Suite 620
Portland, Oregon 97204

Re: K983168
Trade Name: Avant High Speed Handpiece, Avant Fiber Optic High Speed Handpiece
Regulatory Class: I
Product Code: EFB
Dated: September 8, 1998
Received: September 10, 1998

Dear Dr. Cogan:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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

Indications for Use Statement

510(k) Number: _____

Device name: Avant High Speed Handpiece

Indications for Use:

The Avant handpiece will be used by dentists to remove decayed tooth structure, and to cut or alter the shape of teeth so they may be restored to form and function.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983166