DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1998

Douglas L. Cook, DDS, SC
Pertec of Wisconsin, Incorporated
10971 Clinic Road
Suring, Wisconsin 54174 USA

Re: K982105
Trade Name: Oral Potential Meter (OPM)
Regulatory Class: II
Product Code: LFC
Dated: June 24, 1998
Received: July 31, 1998

Dear Dr. Cook:

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

K982105

510(K) Number (if known): K982105

Device Name: Oral Potential Meter

Indications For Use: Caries detection Device
The Oral Potential Meter aids the dental professional in detecting potential caries. Meaurements above 10 millivolts, 1 microamp and 0.01 microwatts x seconds indicates a need for the dental professional to look at potentially carious leasions by also using other means, such as direct exploration, radiographs, etc. The OPM aids in determing potentially active caries and can not detect mineralized caries that have no potenial energy. Remineralized teeth are no longer considered carious.

The OPM is a device that measures and displays voltage and conducts through caries related to metallic restorations in the oral cavity. The dentist may be able to, on visual exam, detect caries at the margins or with x-ray under a restoration with these readings. It also provides a power measurement (energy or joules) integrated over a measured period of time and displays it. The meter has two probes that are used to make the measurements. One is a reference probe, Red, with push-button switch to turn on the meter and initiate the measurements. The other is used as the primary input, Black to the meter's electronics

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

Concurrence of CDRH, Office of device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982105