K972642

EXHIBIT 2

ESTRAD B.V.
Westeinde 46
7711 CL NIEUWLEUSEN
The Netherlands
Phone +31(529)481543
Fax: +31(529)484999
Contact name: H. E. Schuldink

JAN 26 1998

July 10, 1997

510(k) Summary of Safety and Effectiveness per 21 CFR 807.92

1. **Identification of the Device:**
Proprietary-Trade Name: "Perio Control II™"
Classification Name: Probe, Periodontal 76EIX.
Common/Usual Name: Electronic Periodontal Probe Measuring Device

2. **Equivalent legally marketed devices** This product is similar in design and function to the FLORIDA PROBE. 510(k) Number: K875076

3. **Indications for Use (intended use)**
The intended use of the "Perio Control II™" device is to screen patients and to track disease progression in the target population of patients who are suspected of having or already have periodontal disease. Both pediatric and adult patients may be tested.

4. **Description of the Device:**
The Perio Control II™ is used during periodontal examination to measure gingival pocket depth. The pocket depth is displayed on the electronics unit and can be entered in an external computer system, either a PC or a Psion Series 3C)

Also, the eventual occurrence of bleeding on probing can be registered, as well as the presence of supra-gingival plaque. This is judged visually and registered by pressing one of the buttons on the Perio Control II™ handpiece.

The pocket depth is measured by entering the probe tip into the gingival pocket and forcing the filament of the probe up into the sleeve until the sleeve is at a specific reference point. In this position one of the buttons on the Perio Control II handpiece is pressed. The pocket depth is now displayed on the electronics unit.

5. **Safety and Effectiveness, comparison to predicate device.**
The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart

Characteristic	Predicate device: The Florida probe (K875076)	New device: "Perio Control II ™"
Intended Use:	Screen patients and to track disease progression in the target population of patients who are suspected of having or already have periodontal disease. Both pediatric and adult patients may be tested.	Same
Physical characteristics:		
Measuring range	1-10mm	0-10.5mm
Probe tip shape	Rounded edge	spherical
Probe tip dimension	0.4mm	0.5mm
Probe tip material	Titanium	Stainless steel
Sterilization	Autoclave	Same
Accuracy	0.2mm	Same
Probing force	0.23-0.27 N	0.17-0.32 N
Probing pressure	183-215 N/cm^2	100-200 N/cm^2

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Estrad B.V. that the "Perio Control II™" is as safe and effective as the predicate device and has no new indications for use, thus rendering it substantially equivalent to the predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1998

Estrad B.V.
c/o Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K972642
Trade Name: Perio Control II
Regulatory Class: I
Product Code: EIK
Dated: October 22, 1997
Received: October 28, 1997

Dear Mr. Kamm:

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) 594-4613. 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

d) Indications for Use

510(k) Number K972642

Device Name: "Perio Control II ™" Periodontal Probing and Measurement Device.

Indications for Use:
The Perio Control II is used during periodontal examination to measure gingival pocket depth. The pocket depth is displayed on the electronics unit and can be entered in an external computer system, either a PC or a Psion Series 3C.

Also, the eventual occurrence of bleeding on probing can be registered, as well as the presence of supra-gingival plaque. This is judged visually and registered by pressing one of the buttons on the "Perio Control II™" handpiece.

The pocket depth is measured by entering the probe tip into the gingival pocket and forcing the filament of the probe up into the sleeve until the sleeve is at a specific reference point. In this position one of the buttons on the "Perio Control II™" handpiece is pressed. The pocket depth is now displayed on the electronics unit.

The intended use of the "Perio Control II™" device is to screen patients and to track disease progression in the target population of patients who are suspected of having or already have periodontal disease. Both pediatric and adult patients may be tested.

(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 K972642

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)