JAN 2 3 2004

K031809

510(k) Summary

for

Perio Protect Tray

1. **DATE PREPARED**

January 14, 2004

2. **SPONSOR INFORMATION**

Main Office

Perio Protect LLC
3929 Bayless Avenue
St. Louis, MO 63125

Mailing Address

Perio Protect LLC
3929 Bayless Avenue
St. Louis, MO 63125

Contact Person: Duane C. Keller, D.M.D.

(314) 638-4190 (telephone)
(314) 638-3900 (facsimile)

Outside Regulatory Counsel

Gray Cary Ware & Freidenrich LLP
1625 Massachusetts Ave., NW – Ste 300
Washington, DC 20036

(202) 238-7749 (telephone)
(202) 238-7701 (facsimile)

Contact Person: David L. Rosen, R.Ph., J.D.

3. DEVICE NAME

Proprietary Name:	Perio Protect Tray
Common/Usual Name:	Dental Tray
Classification Name:	Disposable Fluoride Tray (per 21 C.F.R § 872.6870 (2002))

4. DEVICE DESCRIPTION AND INTENDED USE

The Perio Protect Tray is a custom fit tray made from impressions of the patents mouth taken by a licensed dentist. The patient impressions are then sent to a specialized dental laboratory which makes a custom fit tray for the individual patient.

The Perio Protect Tray is intended to be used to place solutions of the clinician's choice into gingival crevices or periodontal pockets. The design of the Perio Protect Tray permits placement of solutions deeper into the crevice/pocket than is possible with traditional fluoride trays.

The choice of solution, the frequency of use, and the time the tray is to be in place are a part of the practice of dentistry, and are to be determined by the clinician.

5. PREDICATE DEVICE

Hoyt Laboratories

Disposable Fluoride Tray – K 811154

Such products are now Class I Exempt per 21 C.F.R § 872.6870 (2002)

Substantial Equivalence Comparison

	Delivery of Oral Irrigation Materials	Indication for Use	Design	Materials	Anatomic Sites
Perio Protect Tray	Site specific	Irrigation / solutions	Custom	Elastomeric	Teeth / gingiva
Fluoride Tray Hoyt Laboratories K811154	General area specific	Topical fluoride application	Preformed	Foam	Teeth

6. DEVICE TESTING

PERFORMANCE DATA

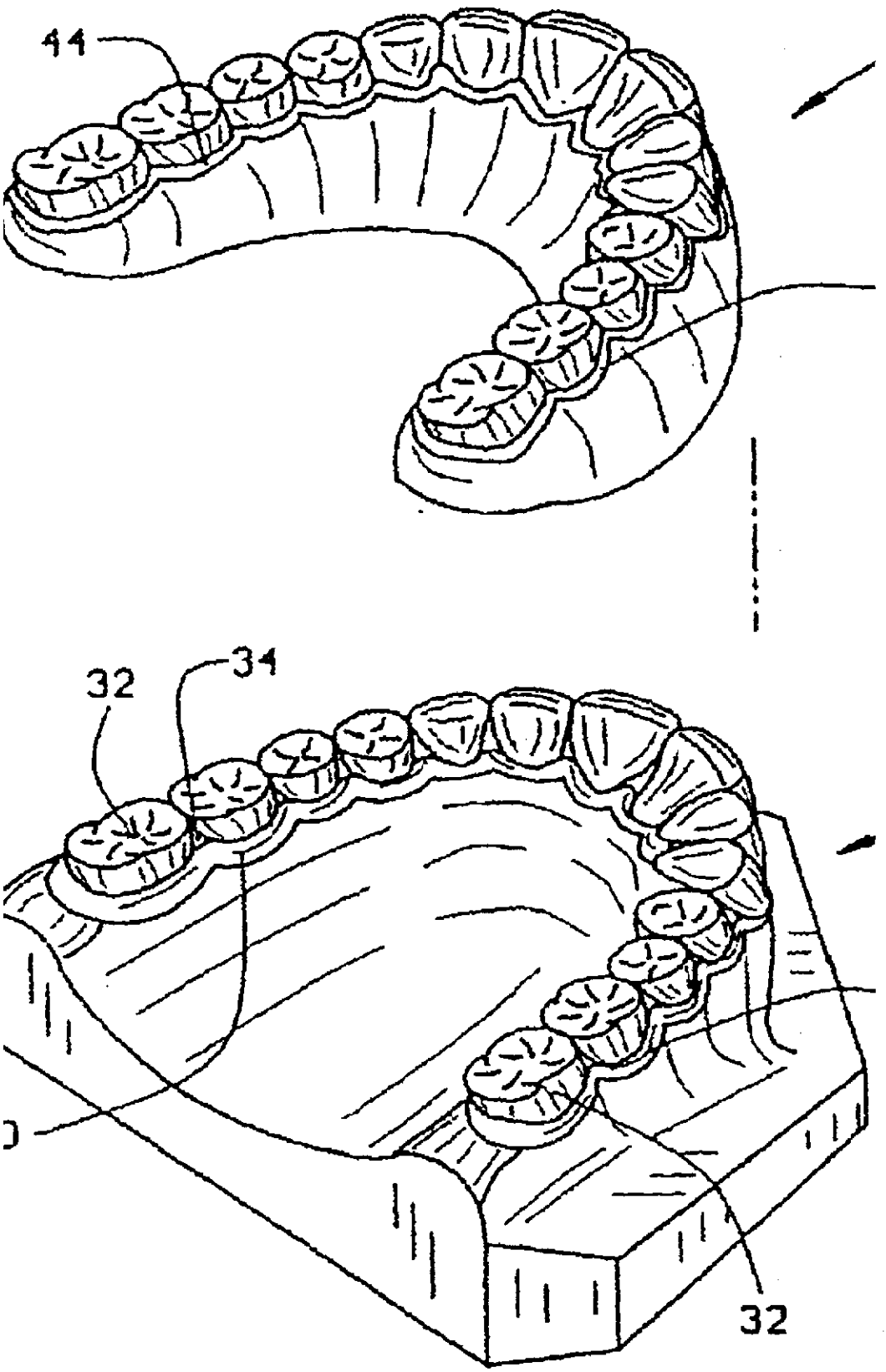
A. Data demonstrating different solutions used in the clinician's practice of dentistry are delivered to the teeth and surrounding tissues by use of the Perio Protect Tray.

Sodium Fluorescein dye was mixed in an aqueous solution and applied to the Perio Protect Tray with one drop of Peroxyl (hydrogen peroxide) gel. Sodium Fluorescein is a phosphorescent dye that can be illuminated under a black light.

The patients wore the trays 10 – 15 minutes in the morning and evening for one day. The patients were examined 24 hours later and a black light was used to illuminate the region around the teeth. Sodium fluorescein dye was observed in the gingival sulcus.

B. The force necessary to remove the Perio Protect Tray was also tested.

Trays were also placed in the patient's mouth. A gram gauge was used to remove the tray from the patient's mouth. Each of these tests was repeated 10 times and an average of the force necessary to remove the tray was computed.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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Perio Protect LLC
C/O Dr. David L. Rosen
Gray Cary Ware & Freidenrich LLP
1625 Massachusetts Avenue NW, Suite 300
Washington, D.C. 20036-2247

Re: K031809/S1
Trade/Device Name: Perio Protect Tray
Regulation Number: 21 CFR 872.6870
Regulation Name: Disposable Flouride Tray
Regulatory Class: I
Product Code: KMT
Dated: October 27, 2003
Received: October 30, 2003

Dear Dr. Rosen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031809

510(k) Number (if known): K031809

Device Name: Trade Name: Perio Protect Tray

Indications for Use:

The Perio Protect Tray is intended to be used to place solutions of the clinician's choice into gingival crevices or periodontal pockets. The design of the Perio Protect Tray permits placement of solutions deeper into the crevice/pocket than is possible with traditional fluoride trays.

The choice of solution, the frequency of use, and the time the tray is to be in place are a part of the practice of dentistry, and are to be determined by the clinician.

PLEASE DO NOT WRITE BELOW THIS LINE
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Concurrence of CDRH, Office of Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K031809

Prescription Use ✓ or Over-The-Counter Use ____
(Per 21 CFR 801.109)