

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

Date: 6/8/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K050486/A<sup>3</sup>

To: Division Director: DE/DAGID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete: (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number). *side summary revision as per my request*

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: *ATK8* *[Signature]*

Date: 6/13/05

Draft #2: 9/8/99  
Draft #3: 1/3/00  
Draft #4: 3/7/03

*DMC 6/13*

**8. 510(k) SUMMARY*****8.1 Submitter's Name and Contact Information***

Submitter Company: Sunstar Butler  
Address: 4635 W. Foster Ave.  
City, State, Zip Chicago, IL 60630

Contact Person: Name: Richard O. Wood  
Phone/Fax: (312) 807-4364  
(312) 827-8189 (Fax)  
Email: rowood@bellboyd.com

Date Prepared: Date: June 6, 2005 (Amendment)

***8.2 Name of Device and Name/Address of Applicant***

Protect™ Tooth Desensitizer  
Sunstar Butler  
4635 W. Foster Ave.  
Chicago, IL 60630

***8.3 Name and Address of Manufacturer***

Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
Liechtenstein

***8.4 Common or Usual Name***

Tooth desensitizer

***8.5 Classification Name***

Varnish, cavity

***8.6 Predicate Device***

Protect is substantially equivalent to Vivasens (K030922), manufactured by Ivoclar Vivadent, Inc. and Orajel Advanced Tooth Desensitizer (K041680).

***8.7 Intended Use***

Protect™ Tooth Desensitizer is a film-like varnish indicated for the treatment of tooth sensitivities.



JUN 7 - 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Sunstar Butler  
C/O Mr. Richard O. Wood  
Bell, Boyd & Loyd, LLC  
70 West Madison Street, Suite 3300  
Chicago, Illinois 60602

Re: K050486  
Trade/Device Name: Protect™ Tooth Desensitizer  
Regulation Number: 872.3260  
Regulation Name: Cavity Varnish  
Regulatory Class: II  
Product Code: LBH  
Dated: April 29, 2005  
Received: May 2, 2005

Dear Mr. Wood:

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 (240) 276-0115. 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/industry/support/index.html>.

Sincerely yours,



Jenette Y. Michien MD.

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

510(k) Number (if known): K050486

Device Name: Protect™ Tooth Desensitizer

**1. INDICATIONS FOR USE:**

Protect™ Tooth Desensitizer is a film-like varnish indicated for the treatment of tooth sensitivities.

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K050486

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use  X