Sylphar

K122708

Appendix E

JAN 1 4 2013

510(k) Summary in accordance with 21 CFR 807.92(c)

Device Name:	Sylphar Remesense for Sensitive Teeth
Type of 510(k) submission:	Traditional
Date of Submission:	30 August 2012
Manufacturer:	Sylphar N.V. Xavier de Cocklaan 42 B-9831 Deurle Belgium
FDA Registration Number:	3004847139
510(k) Owner:	Sylphar N.V. Xavier de Cocklaan 42 B-9831 Deurle Belgium
Phone: **Fax:**	+32 (0)9 321 70 80 +32 (0)9 321 70 90
FDA Registration Number:	3006673777
Owner/Operator Number:	10034642
510(k) Submitter and Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy Phone: +39 06 578 2665 Fax: +30 06 574 3786 Email: rgray@donawa.com
FDA Product Code:	LBH
FDA Regulation Number:	872.2360
FDA Classification Name:	Varnish, Cavity
Classification Panel:	Dental
Common Name:	Tooth Desensitizer
FDA Panel:	Dental
FDA Classification:	Class II
FDA Identification:	Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

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Indications for Use: Remesense for Sensitive Teeth is intended for use as a tooth desensitizer.

Device Description:

'Sylphar Remesense for Sensitive Teeth' is an identical device to 'Remedent Remesense', cleared for marketing in the US by FDA under K082594.

'Remedent Remesense' was cleared as a 'prescription only' (Rx) device. The purpose of this 510(k) submission is to present additional data so that 'Sylphar Remesense for Sensitive Teeth' may be cleared by FDA for marketing as an 'over-the-counter' (OTC) device in addition to a prescription device under a new name.

The labeling, both on the device box and in the instructions sheet provided in the box, has however been revised to include the new product name and provide additional information to better accommodate sale as an OTC device.

The component parts of the device are:

- Outer box
- Pre-formed dental tray in a plastic bag
- 3 x Two foam strips impregnated with glycerin, aqua, dipotassium oxalate, aroma, EDTA, methylparaben, citric acid and saccharin
- Plastic packaging for the foam strips, with foil covering
- Instruction sheet

Performance Data:

Sylphar Remesense for Sensitive Teeth uses dipotassium oxalate crystals to block the tubules in the teeth of patients suffering from acute tooth hypersensitivity. By blocking the tubules, it stops the signals from hot or cold food reaching the dental nerve, providing a rapid remedy for hypersensitivity.

In order to confirm the safety and effectiveness of Sylphar Remesense for Sensitive Teeth as an OTC product, two studies were performed:

- The first was a questionnaire sent to US dentists
- The second was a usability study of the subject device

The conclusion from the results of the questionnaire was that dentists are routinely prescribing Rx tooth desensitizing products for patient home use, and that any additional information provided is merely a reinforcement of product instructions, rather than anything new related to safety or effectiveness. The additional instructions provided by the dentists answering the questionnaire have been reviewed and, where relevant to the subject device, it has been ensured that these are included within the instructions drafted for the subject device.

The conclusion from the usability study on the subject device was that patients suffering from tooth hypersensitivity are able to select the product from a display of other dental products, and also that patients who have conditions that are contraindicated for use of the subject device are unlikely to select the product. Several recommendations for improvement of the product labeling resulted from the usability study.

Comparison with predicate devices:

The predicate devices selected for comparison with the Sylphar Remesense for Sensitive Teeth are:

Predicate Device 1:..... Remedent Remesense
510(k) Sponsor: ..... Remedent N.V.
510(k) Number: K082594

Sylphar

Clearance Date: ..... 19 March 2009
FDA Product Code: ..... LBH
Classification Name: ..... Varnish, Cavity
Regulation No: 872.3260

Predicate Device 2: ..... Centrix Senzzzz Away
510(k) Sponsor: ..... Centrix Inc
510(k) Number: K120176
Clearance Date: ..... 25 July 2012
FDA Product Code: ..... LBH
Classification Name: ..... Varnish, Cavity
Regulation No: 872.3260

Conclusion:

Based on the information contained within this submission, it is concluded that 'Sylphar Remesense for Sensitive Teeth' is substantially equivalent to the identified predicate devices already in interstate commerce within the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 14, 2013

Sylphar N.V.
C/O Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania 10
Rome, Italy 00153

Re: K122708
Trade/Device Name: Sylphar Remesense for Sensitive Teeth
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 3, 2013
Received: January 11, 2013

Dear Mr. Gray:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): ~~Not known~~ K122708

Device Name: Sylphar Remesense for Sensitive Teeth

Indications for Use:

Remesense for Sensitive Teeth is intended for use as a tooth desensitizer

Prescription Use (Part 21 CFR 801 Subpart D)	☒	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	☒

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.14 14:35:39 -05'00'

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

510(k) Number: K122708