K123823

angelus®
science and technology

MAY 3 1 2013

SECTION 9

510(K) **SUMMARY OF SAFETY AND EFFECTIVENESS**

Proprietary Name	Interlig
Date Prepared	May 1, 2013
Submitter	Angelus Industria de Productos Odontologicos Waldir Landgraf, 101 Londrina, Brazil 86031-3200 Telephone: +55 43 2101 3200
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077
Common Name	Glass fiber reinforcement material
Classification Name	Tooth Shade Resin Material
Regulation Number & Product Codes	EBF – 872.3690
Proposed Regulatory Class	Class II
Predicate Device Identification	Splint It K972985

Description of Proposed Device

Interlig is a structure of intertwined glass fibers pre-impregnated with light-cured composite resin.

Indications for Use

Interlig is indicated for:

- Splinting periodontal involved and mobile teeth to prevent movement
- To reinforce full denture and partial denture repairs
- As a matrix between abutment teeth for receiving a temporary replacement tooth
- As an aid in the reinforcement of temporary crowns and bridge work
- As a space maintainer for orthodontic involved teeth

Substantial Equivalence

Interlig has the same intended use and similar technical characteristics as Splint It K972985. The indications for use, materials, form factor, performance and safety characteristics between Interlig and Splint It are the same.

Conclusion

Based on the information provided in this premarket notification, we can conclude that Interlig is as safe and effective as the predicated device.

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

May 31, 2013

Angelus Industria de Productos Odontologicos
C/O Ms. Lilian Llull
TechLink International Consulting
18851 North East, 29th Avenue
Suite 720
AVENTURA FL 33180

Re: K123823
Trade/Device Name: Interlig
Regulation Number: 21 CFR 872.3690
Regulation Name: Endodontic Stabilizing Splint
Regulatory Class: II
Product Code: EBF
Dated: May 1, 2013
Received: May 2, 2013

Dear Ms. Llull:

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 contact 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. 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 -S

Kwame Ulmer M.S.
Acting Division 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

Interlig is indicated for: K123823

- Splinting periodontal involved and mobile teeth to prevent movement
- To reinforce full denture and partial denture repairs
- As a matrix between abutment teeth for receiving a temporary replacement tooth
- As an aid in the reinforcement of temporary crowns and bridge work
- As a space maintainer for orthodontic involved teeth

Prescription Use _____X___ (Part 21 CFR 801 SubpartD) AND/OR
Over-The-Counter Use _____ (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

Susan Runner DDS MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000087950
Date: 2013.05.31 09:17:49 -04'00'

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

510(k) Number: K123823