K031070

JUL 3 2003

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason, Sr. Regulatory Affairs Specialist
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Date of Submission:	April 2, 2003
Classification Name:	Denture Relining, Repairing, or Rebasing Resin (21 CFR 872.3760)
Trade or Proprietary or Model Name:	Carbon Fiber Bridge
Legally Marketed Device(s):	Ribbond – Triaxial (K013881) Everstick™ (K011788) Stick™ (K003333)

Device Description:
The Carbon Fiber Bridge provides an alternative to traditional gold/metal framework in the creation of denture bases. The Carbon Fiber Bridge is sold in the form of a kit and uses carbon fibers infused with a 2-part polymer, which when hardened together becomes the denture frame. The kit contains a carbon fiber tube, the 2-part polymer resin, titanium retention wires, protection gloves and mask, and instructions for use.

The shape of the carbon fiber bridge is formed using a model of the patient's jaw. Laboratory cylinders and perforating tips are placed in the model. Using a mounting tool, the carbon fiber tube is placed over the perforating tips, piercing the tube and spreading the carbon fibers. Titanium retention wires are then placed in proposed teeth locations, and the framework is polymerized by heat. After polymerization, the carbon fiber tube and retention wires are trimmed. The carbon fiber frame is then painted, using standard laboratory materials, to a preferred color as desired by the laboratory and the prosthetic teeth are attached with common dental acrylic materials wrapped around the framework.

The finished prosthetic reconstruction is then ready to be placed in the patient's jaw using existing techniques in the placement of endosseous implants and dentures.

Indications for Use:
The Carbon Fiber Bridge is indicated for use as a denture base material providing reinforcement of prosthetic reconstructions in the treatment of fully or partially edentulous patients in order to restore the patient's chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Elizabeth J. Mason
Sr. Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K031070
Trade/Device Name: Carbon Fiber Bridge
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI
Dated: April 02, 2003
Received: April 30, 2003

Dear Ms. Mason:

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. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Statement of Indications for Use

510(k) number *(if known)*: K031070

Device Name: Carbon Fiber Bridge

Indications for Use:
The Carbon Fiber Bridge is indicated for use as a denture base material providing reinforcement of prosthetic reconstructions in the treatment of fully or partially edentulous patients in order to restore the patient's chewing function.

(Please do not write below this line – Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Ron Mulry for MSR

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

510(k) Number: K031070