K112445

OCT 2 8 2011

510(k) Summary
Tokuyama Dental Corporation
SOFRELINER TOUGH S
Denture Relining, Repairing, Or Rebasing Resin Device

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1)

(i) 510(k) Submitter

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo 110-0016
Japan
Phone: 011-81-3-3835-2261

(ii) 510(k) Submitter Contact

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331
Email: barritt@fr.com

(iii) Preparation Date

August 3, 2011

807.92(a)(2)

Trade or Proprietary Name:	SOFRELINER TOUGH S
Common Name:	denture relining, repairing, or rebasing resin material
Classification Name:	resin, denture, relining, repairing, rebasing
Product Code:	EBI

807.92(a)(3)

The SOFRELINER TOUGH S device is substantially equivalent for purposes of FDA medical device regulations to multiple predicate devices, namely Tokuyama's own TOKUYAMA SOFRELINER (K#982537), TOKUYAMA SOFRELINER TOUGH (K#030663), and GC America's GC RELINE ULTRA SOFT (K#990736).

807.92(a)(4)

The SOFRELINER TOUGH S denture relining, repairing, or rebasing resin device is a prescription addition-cured silicone chairside soft lining material for removable dentures. It is indicated for use as a denture reliner.

The main components of the SOFRELINER TOUGH S device are:

1) A paste consisting of a base and catalyst;
2) A primer packaged separate used for bonding to the acrylic surfaces; and
3) Various accessories, namely a spatula, brush, drip-cap, drip-cup, mixing tip, coarse point, finish wheel, and washer

Nearly all ingredients used in the SOFRELINER TOUGH S denture relining, repairing, or rebasing device are either commonly used in similar dental devices or have been subjected to extensive biocompatibility testing. However, the paste of the SOFRELINER TOUGH S does contain one new ingredient and thus toxicity testing was performed, namely cytotoxicity, sensitization, irritation, subchronic systemic toxicity, and genotoxicity.

The SOFRELINER TOUGH S denture relining, repairing, or rebasing resin device does not come sterilized and is not intended to be sterilized prior to use.

807.92(a)(5)

The SOFRELINER TOUGH S denture relining, repairing, or rebasing resin device is for use as a denture reliner.

807.92(a)(6)

The SOFRELINER TOUGH S device has the same basic technological characteristics in terms of design, material, and chemical composition as the predicate devices identified above. The SOFRELINER TOUGH S device does not have an energy source.

Specifically, for purposes of design the device has the same basic design and performance characteristics as Tokuyama's own TOKUYAMA SOFRELINER (K#982537), TOKUYAMA SOFRELINER TOUGH (K#030663), and GC America's GC RELINE ULTRA SOFT (K#990736). For purposes of material composition, the device has the same basic properties as TOKUYAMA SOFRELINER TOUGH.

807.92(b)(1)

Non-clinical testing of the physical properties of the SOFRELINER TOUGH S device, including depth of penetration, difference between mean depth of penetration at 24 hours and 28 days, depth of penetration ratio "R", consistency, 2 hour penetration, 7 day penetration, and penetration ratio were conducted in accordance with ISO 10139-1: 1991 and ISO 10139-2: 1999. Other testing included appearance, working time, and setting time.

807.92(b)(2)

There were no clinical tests performed for the SOFRELINER TOUGH S device.

807.92(b)(3)

Based on the non-clinical testing conducted of the physical properties of the SOFRELINER TOUGH S device and the material composition review in comparison to the predicate devices and biocompatibility testing as described above, it is concluded that the SOFRELINER TOUGH S device is as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 2 8 2011

Tokuyama Dental Corporation
C/O Mr. Keith A. Barritt, Esq.
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005

Re: K112445
Trade/Device Name: Sofreliner Tough S
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Codes: EBI
Dated: August 12, 2011
Received: August 24, 2011

Dear Mr. Barritt:

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,

for

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

Enclosure

Indications for Use

510(k) Number (if known): unknown K112445

Device Name: SOFRELINER TOUGH S

Indications for Use:

The SOFRELINER TOUGH S denture relining, repairing, or rebasing resin device is for use as a denture reliner.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (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)

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

510(k) Number: K112445

40743046.doc