K072968

510 (K) SUMMARY
TOTAL-GARD CORPORATION
STRESSGARD ™ NIGHT GUARD

510(K) NUMBER:_____ JUL - 1 2008

I SUBMITTER'S NAME, ADDRESS, TELEPHONE NUMBER, CONTACT PERSON AND DATE OF PREPARATION

Total-Gard, Corporation
800 West Cummings Park
Suite 1550
Woburn, MA 01801

Contact: Glenn Bancroft, Vice President

Telephone: 888.447.1807
Facsimile: 781.376.0638

OR

Bell & Izzi, LLC
70 West Foster Street
Melrose, MA 02176

Contact: Louis P. Izzi, Esq.

Telephone: 781.665.3360
Facsimile: 781.665.1321

Date Prepared: October 17, 2007

II NAME OF DEVICE

Stressgard ™ Night Guard

III NAME OF SPONSOR, ADDRESS, TELEPHONE NUMBER AND CONTACT PERSON

Total-Gard, Corporation
800 West Cummings Park
Suite 1550
Woburn, MA 01801

Contact Person: Glenn Bancroft, Vice President

Telephone: 888.447.1807
Facsimile: 781.376.0638

510 (K) SUMMARY
TOTAL-GARD CORPORATION
STRESSGARD ™ NIGHT GUARD

510(K) NUMBER:_____

IV COMMON OR USUAL NAME

Dental Protector
Nightguard

V PREDICATE DEVICES

Dental Concepts, LLC, The Doctor's® Nightguard™ (K053580)
Dentek Oral Care, Inc., Comfort Fit Nightguard (K072147)
Splintek-Power Products, Inc., SleepRight® (K071404)

VI INTENDED USE/INDICATIONS FOR USE

The Stressgard™ Night Guard is indicated for protection from night-time teeth grinding, clenching and bruxism. It is intended to reduce damage to teeth and to prevent the noise associated with teeth grinding or bruxing.

VII TECHNOLOGICAL CHARACTERISTICS

The TotalGard™ Stressgard™ Night Guard is composed entirely of a soft, flexible semitransparent FDA compliant material, Monprene® thermoplastic elastomers. As packaged, the Stressgard ™ Night Guard is ready for use by the consumer. If desired, the Stressgard™ Night Guard is easily trimmed by the consumer, however it requires no forming or molding for use.

VIII PERFORMANCE DATA

No performance data is required in support of this 510(k) Notification.

IX SUBSTANTIAL EQUIVALENCE

The TotalGard™ Stressgard™ Night Guard is as safe and effective as the predicate devices. With respect to the physical composition of the Stressgard™ Night Guard, not unlike the predicate devices, the Stressgard™ Night Guard is comprised of FDA compliant Monprene® which has been determined to be safe and effective for use in FDA cleared medical devices. The Stressgard™ Night Guard has similar intended uses and indications as the predicate devices and the labeling and instructions are appropriate for over the counter use. As a result, the TotalGard™ Stressgard™ Night Guard is substantially equivalent to the predicate devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2008

TotalGard Corporation
C/O Mr. Louis P. Izzi
Bell & Izzi, LLC
70 West Foster Street
Melrose, Massachusetts 02176

Re: K072968
Trade/Device Name: Stressgard™ Night Guard
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OBR
Dated: May 22, 2008
Received: May 23, 2008

Dear Mr. Izzi:

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,

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

K072968

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Stressgard™ Night Guard

Indications For Use:

The Stressgard™ Night Guard is indicated for protection from night-time teeth grinding, clenching and bruxism. It is intended to reduce damage to teeth and to prevent the noise associated with teeth grinding or bruxing.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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