K014079

510(k) Premarket Notification Summary of Safety and Effectiveness Information	Dr. Hays Bite Guard February 3, 2002

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

FEB 22 2002

1. **Device Name:**

   Trade Name: **Dr. Hays Bite Guard**
   Common Name: Night Guard
   Classification Name: Device, Jaw Repositioning

2. **Establishment Name & Registration Number:**

   Name: Inventive Resource, Inc.
   Number: Pending

3. **Classification:**
   Unclassified Device

   Product Code(s): LQZ
   Device Class: unclassified
   Classification Panel: Anesthesia Devices Panel & Dental Device Panel

4. **Contact Person:**
   Mr. John A. Paoluccio
   Inventive Resources, Inc.
   5038 Salida Blvd.
   Salida, CA 95368
   209.545.2616 – 209.545.3533 - fax

   Submission Correspondent:
   Mr. David W. Schlerf
   Buckman Company, Inc.
   200 Gregory Lane, Suite C-100
   925.356.2640 / 925.356.2654 FAX

5. **Description of the Device:**
   The **Dr. Hays Bite Guard** is designed to assist in the treatment and management of occlusal disorders resulting in teeth grinding, jaw clenching, and mandibular muscle spasm. The device is comprised of a thin horseshoe shaped plastic (polycarbonate, Lexan) tray filled with a thermoplastic agent (Elvax). The device is supplied to health care practioners to heat, mold, and otherwise custom fit and trim each device to the patient. **Materials:** the **Dr. Hays Bite Guard** is made of Lexan and Elvax, the same materials as the Snore Guard device, cleared under K882303.

   The device is supplied **Non-Sterile.**

   The device is packaged in "clean only" condition but is free of manufacturing debris and/or residues. Components are inspected after processing to evaluate and document the removal of manufacturing residue and debris. However, it is recommended that the device be removed from its shipping and packing materials and washed with warm soap and water before use. The device may not be autoclaved.

Sanitizing. The **Dr. Hays Bite Guard** is non-sterile and must be cleaned and sanitized before first and all subsequent uses. Wash the device thoroughly with hot water using a typical commercial detergent or anti-bacterial soap. Rinse completely in running warm tap water. Allow to air dry and return the device to its case. See Appendix I for complete instructions.

Packaging. Materials used in the packaging of the device are typical injection molded plastic boxes. Carton and shippers are made from appropriate paper based products.

Storage. The device should be stored clean and dry. The location should be at the bedside or bathroom on in locations where ambient temperatures do not exceed 130 degrees F.

6. **Comparison to Predicate Device(s):**
Dr. Hays Bite Guard may be directly contrasted with the following equivalent devices:

- ***SnoreGuard*™**K882303.
- ***Best Bite Decluder*™** K980953
- ***NTI Clenching Suppression System*** K981546

Summary Basis for Equivalence and Comparison Table:

Based on the available information concerning the referenced comparison devices, these devices are similar in that:

The devices have the same intended use and indications for use.
The devices are made of the same basic materials.
The devices have a similar design, form and function.

The referenced comparison devices demonstrate that the **Dr. Hays Bite Guard** is substantially equivalent . The table on the following page compares the available legally marketed devices.

Comparison Table:

FEATURE	Dr. Hays Bite Guard	Snore Guard	Best Bite	NTI System	SE?
Indications for Use:	Protecting against teeth grinding, bruxism and jaw clenching. Short-term pain relief from muscle spasm pain due to occlusal interference. For the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle. The device is custom made for the individual.	Snoring – sometimes used for Bruxism	Same	Same	Yes
Materials:	Lexan & Elvax	Same	Thermoplastic	Thermoplastic	Yes
Design:	Custom molded mouth guard	Same	Same	Same	Yes
Prescription Device:	Yes	Same	Same	Same	Yes
Reusable:	Yes - Single patient	Yes	Yes	Yes	Yes
Method of Disinfection:	Warm water, soap & toothbrush	Same	Same	Same	Yes
K-Number:	Pending	K882303	K980953	K981546	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Inventive Resources, Incorporated
C/O Mr. David W. Schlerf
Buckman Company
200 Gergory Lane, Suite C-100
Pleasant Hill, California 94523-3389

Re: K014079
Trade/Device Name: Dr. Hayes Bite Guard
Regulation Number: None
Regulation Name: Night Guard
Regulatory Class: Unclassified
Product Code: LQZ
Dated: November 9, 2001
Received: December 11, 2001

Dear Mr. Schlerf:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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). 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K014079

510(k) Number **K014079**

Device Name: **Dr. Hays Bite Guard**

Indications For Use:

- Protecting against teeth grinding, bruxism and jaw clenching.
- Short-term pain relief from muscle spasm pain due to occlusal interference.
- For the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth by the temporalis muscle. The device is custom made for the individual.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014079

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)