K052553

DEC 2 2 2005

5. 510K Summary (As required by section 807.92(c))

5.1.
Owners name and contact person (807.92 (a)(1)):
Dr. Russell Henry Ashleigh Samuels.

Owners address: 7 Cricket Lane,
Loughborough,
Leicestershire,
LE11 3PD,
England, UK.

Telephone number: 01509 (0044 1509) 216480.

Summary prepared: 9th September 2005.

5.2.
Device classification name (807.92 (a)(2)): Headgear, Extraoral, Orthodontic.

Trade name of device: Nitom Locking facebow.

The common name: Orthodontic facebow.

5.3.
An identification of the legally marketed device to which the submitter claims equivalence is (807.92 (a) (3)):

Classification Advisory committee:	Dental
Product code:	DZB.
Regulation number:	872.5500
Device name:	Nitom Locking facebow
510K number:	K980245.

5.4.
Description of The Device (807.92 (a)(4)):
The Nitom Locking facebow is a type of orthodontic facebow used in Orthodontic treatment with a neckstrap or headcap to hold or move the upper back teeth backwards. The Nitom Facebow has two catches or locks on the inner bow to prevent it accidentally coming out at night. It is attached to extra oral traction tubes of the patients fixed orthodontic appliance on the upper first molars. It is usually worn by the patient in the evening and at night. It improves the anchorage of the upper back teeth. It is made of stainless steel.

5.5.
Statement of intended use of the device (807.92 (a)(5)).
The nitom locking facebow is used by the Dental speciality of Orthodontics in the treatment of some orthodontic patients. The patients are usually children aged 9 to 16 years of age. The device is usually worn in the evenings and at night time while asleep. It is attached to a headcap or neckstrap at one end and to the upper molar teeth at the other end. It uses the back of the head or neck to apply a backward force to the upper molar teeth to prevent them moving forward during orthodontic treatment. It is a very useful device in helping to achieve a successful outcome in some cases.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2005

Dr. Russell Henry Ashleigh Samuels
Russell Samuels Orthodontic Design
7 Cricket Lane
Loughborough, Leicestershire
LE11 3PD England
UNITED KINGDOM

Re: K052553
Trade/Device Name: Nitom Locking Facebow
Regulation Number: 872.5500
Regulation Name: Extraoral Orthodontic Head Gear
Regulatory Class: II
Product Code: DZB
Dated: November 22, 2005
Received: December 2, 2005

Dear Dr. Samuels:

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.

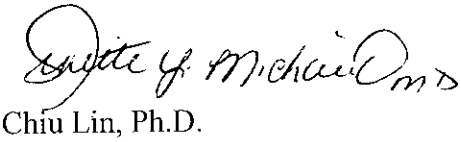
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

K052553

Indications for Use

510(k) Number (if known): K052553

Device Name: Nitom Locking Facebow

Indications For Use: The Nitom Locking facebow is a type of orthodontic facebow used in Orthodontic treatment with a neckstrap or headcap to hold or move the upper back teeth backwards. It has two catches or locks on the inner bow to prevent it accidentally coming out at night.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

K052553