I. 510(k) Summary of Safety and Effectiveness

JUL 0 8 2003

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Contact Person: Patrick J. Strong or Mary Lou Strong

Description of the Device:

Trade name:	The SUAD™ Device
Descriptive name:	Mandibular advancement device/appliance (MAD)
Common Name:	Sleep apnea/Anti-snoring device
Product code:	LRK Anti-snoring device
Device Class:	Class II
Establishment Registration Number:	None
Intended Use:	To reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA).

The Removable Herbst Appliance is the predicate device for the SUAD™ Device, having all the same functional characteristics. The Removable Herbst Appliance (510(k) K955822) is a custom-fitted mandibular device that allows patients to move their jaw laterally and vertically without disengaging the appliance. The device is adjusted to provide the anticipated relief of the condition by moving the mandible forward in 1mm increments by adding advancement shims onto the posts.

The SUAD™ Device has the following modifications: the combination of the materials used, the assembly and the fabrication technique. Detailed drawings of The SUAD™ device are available in the patent, Patent No. US 6,418,933 B1 [Reference 1].

1. 510(k) Summary of Safety and Effectiveness (continued)

The SUAD™ Device functions in a similar manner to other comparative predicate devices and the intended uses are the same (See Table 1). The general differences or modifications between the device and predicate devices are minor and do not raise new safety concerns. Table 2 lists the risks identified for this device and summarizes how Strong Dental Inc. has addressed the risk.

The casted framework is substantially equivalent to the casted framework used in dentures used prior to 1976. The "tube and rod" assembly of the pivot and tube is substantially equivalent to the Herbst appliance. The angle of the connecting tube to the pivot has been changed to allow for greater stability of the appliance. The framework is used to strengthen the device. The smooth "buttons," frames that cover all the occlusal and incisal surfaces, and the use of the vacuum-formed thermo-plastic to hold the appliance results in less exposed wires.

I. 510(k) Summary of Safety and Effectiveness (continued)

Table 1. Substantial Equivalence Comparison

Attribute	SUAD™	Herbst	Klearway	Silencer	TAP
USE					
Intraoral device	Yes	Yes	Yes	Yes	Yes
Reduce snoring	Yes	Yes	Yes	Yes	Yes
Reduce obstructive sleep apnea	Yes	Yes	Yes	Yes	Yes
DESIGN					
Removable device	Yes	Yes	Yes	Yes	Yes
Custom fit	Yes	Yes	Yes	Yes	Yes
Adjustable	Yes	Yes	Yes	Yes	Yes
Allows lateral and vertical movement	Yes	Yes	Yes	Yes	Yes
Clasps required	No	Yes	Yes	Yes	Yes
Frames cover all occlusal and incisal surfaces	Yes	Yes	Yes	Yes	Yes
Buttons attached to frames to attach conventional elastics	Yes	No	No	No	No
Angle of upper connecting tube redirected for greater stability of the upper form	Yes	No	No	No	No
Casted framework inserted into upper and lower frames	Yes	No	No	No	No
MATERIALS					
Base material, vinyl	Yes	Yes	Yes	Yes	Yes
Ethylene acrylic overlay	Yes	Yes	Yes	Yes	Yes
Steel metal components	Yes	Yes	Yes	Yes	Yes
Casted metal framework	Yes	No	No	No	No
TESTING					
Not applicable	Yes	Yes	Yes	Yes	Yes

I. 510(k) Summary of Safety and Effectiveness (continued)

Table 2. Risk Profile

Identified risk	Special controls
Intraoral gingival, palatal, or dental soreness	The internal framework and specific materials used provides for a comfortable fit.
Obstruction of oral breathing	The angle of the upper connecting tube has been redirected, allowing for greater stability of the upper form. With the retruded force of the mandible, the new direction of the tube forces the upper frame to stay in a properly seated position.
Loosening or flaring of lower anterior teeth or general tooth movement	The frames are designed to cover all the occlusal and incisal surfaces.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Strong Dental Incorporated
C/O Clyde A. Takeguchi, Ph. D.
Phoenix Regulatory Associates, Limited
21525 Ridgetop Circle, Suite 240
Sterling, Virginia 20166

JUL 0 8 2003

Re: K023836
Trade/Device Name: SUAD™ Device
Regulation Number: 21 CFR 872.5570
Regulation Name: Anti-Snoring Device
Regulatory Class: II
Product Code: LRK
Dated: April 11, 2003
Received: April 11, 2003

Dear Dr. Takeguchi:

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.

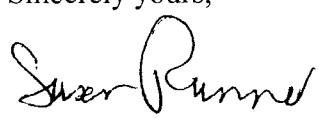
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Sincerely yours,



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

Enclosure

II. Indications for Use

510(k) Number: K023836

Device Name: SUAD™ Device

A custom-fitted mandibular repositioning device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea.

Contraindications:

The device is contraindicated for patients who:

- Have central sleep apnea
- Have severe respiratory disorders
- Have an edentulous arch
- Have loose teeth or advanced periodontal disease
- Are under 18 years of age.

Kosi Mehy for MSP

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

510(k) Number: K023836