JAN 2 8 2003

K023070

510(k) SUMMARY
FOR
SODEM HIGH SPEED SYSTEM (PNEUMATIC)
INCLUDING THE DRILL GUIDE ATTACHMENT

1. COMPANY NAME AND ADDRESS

Applicant:	**Sodem**systems Sodem Diffusion SA 110, Ch. du Pont-du-Centenaire CH-1228 Geneva, Switzerland
Contact Person:	Carole BURNIER
Tel:	+41 22 794 96 96
Fax:	+41 22 794 45 46
Manufacturing site:	**Sodem**systems Sodem Diffusion SA 110, Ch. du Pont-du-Centenaire CH-1228 Geneva, Switzerland
Date:	.....09/10/02.....

2. DEVICE NAME

Classification Name:	Surgical instrument motors and accessories/attach nent pneumatically powered
Proprietary Name:	Sodem High Speed System (Pneumatic)
Common Name:	Powered Surgical Drill

3. PREDICATE DEVICES

The Sodem High Speed System (Pneumatic) is very similar in terms of use and technological characteristics to products currently on the market (Anspach Black max / Micromax).

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4. DEVICE DESCRIPTION

The Sodem High Speed System is a modular pneumatically powered high speed instrument system consisting of a hand piece, adapters and accessories/attachments (spindles, burs...) used to cut hard tissue or bone.

The Sodem High Speed System (Pneumatic) is a complete system including:
- a High Speed motor,
- a foot pedal,
- dedicated hoses to connect the motors and the foot pedal,
- adapters (angled adapter)
- attachments/spindles, (angled attachments, straight attachments standard and tapered, craniotomes)
- drills, burs and cutters

The Sodem High Speed System (Pneumatic) for use in ENT applications is the same product as the Sodem High Speed System (Pneumatic) already cleared for Neurology, Orthopedic and General plastic surgery (K954717, K954080, K955174).

5. INTENDED USE

The Sodem High Speed motor allows the fixation of spindles, adapters and attachments, which operate with drills, burs and cutters for drilling, cutting and sculpting hard tissue and bone for different applications and surgeries.

The system is intended for use in Ear Nose and Throat (plastic reconstructive surgery applications.

6. BASIS FOR CLAIM OF SUBSTANTIAL EQUIVALENCE

The Sodem High Speed System (Pneumatic) claims substantial equivalence to other currently marketed high-speed Pneumatic power systems. This device is substantially equivalent to Anspach Black Max/ Micromax System (see the attached table of comparison)

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	Sodem High Speed System (Pneumatic)	Anspach Black Max/Micromax
510(k) Number	***current submission***	***K960630 / K965080***
Used in ENT surgery	*Yes*	*Yes*
Pneumatic power source	*Yes*	*Yes*
Drill Function	*Yes*	*Yes*
Supplied non sterile	*Yes (except burs)*	*Yes*
Recommended sterilization by steam	*Yes*	*Yes*
Patient contact materials: Principally surgical stainless steel	*Yes and titanium see § 7.3*	*Yes*
Angled nose piece	*Yes*	*Yes*
Foot pedal	*Yes*	*Yes*
Spindles multiple length	*Yes*	*Yes*
Change burs without wrench	*Yes*	*Yes*
Change spindles without wrench	*Yes*	*Yes*
Motor speed (RPM)	*0-85'000 rpm*	*0-80'000 rpm*
Rotation mode	*Forward only*	*Forward/Reverse*

Intended use

The Sodem High Speed System (Pneumatic) and predicate Pneumatic instruments share the same clinical applications and intended used (For Anspach and Linvatec: Ear, nose and throat surgery [Plastic reconstructive surgery]).

Materials

Patient contact materials for all systems consist of surgical materials and principally surgical stainless steel. We use also Titanium Ti 6-Al 4-V for specific spindles. This titanium has a common use in prosthetic implants (ISO 5832-3).

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Sterility Status

All systems are supplied non-sterile except drills and burs (special 510k N° K994175 for sterile drills and burs), requiring reprocessing between surgical applications. Sterilization of all systems is accomplished using steam. All systems require decontamination after use, and resterilization by the user facility.

System Description

Motor

All cited systems are operated using a pneumatic power source controlled by a foot pedal. For all systems, users can increase or reduce speed with a foot pedal.

The nominal power output of the Sodem High Speed System is identical or substantially equivalent to the other commercially available pneumatic motors (Linvatec, Anspach). The drill speed of the Sodem High Speed System (Pneumatic) is adjustable from 0-85'000 rpm, the drill speed of the Anspach motors system is adjustable from 0-80'000 rpm.

Accessories

The Sodem High Speed System (Pneumatic) and predicate systems consist of various attachments (burs, spindles). All offer a wide variety of accessories including but not limited to chuck, adapters, spindles and burs. The technical characteristics of the various adapters are identical or similar. That is, adapters allow the use of hand pieces with various power system accessories.

All products (Sodem, Linvatec and Anspach) have an angled nose.

All systems feature to ability to change burs and spindles without a need of a wrench.

Some systems have a specific attachment for making hole in bone with adjustable depth. The Sodem High Speed System has this kind of attachment (PN 3105DG : Drill Guide Attachment), Anspach Micromax / Black Max Systems have two attachments called Adjustable Drill Guide and Controlled Depth Attachment.

Based on the above comparison, SodemSystems believes that the Sodem High Speed System (Pneumatic) including the Drill Guide Attachment is substantially equivalent to the systems cited, that any differences between the Sodem High Speed System (Pneumatic) and these other currently available powered systems are minor and raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2003

Sodemsystems
c/o Carole Burnier
Quality & Regulatory Affairs Manager
Sodem diffusion sa
110, ch. du Pont-du-Centenaire
CH – 1228 Geneva
Switzerland

Re: K023070
Trade/Device Name: Sodem High Speed System (Pneumatic)
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: December 12, 2002
Received: December 12, 2002

Dear Ms. Burnier:

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) 594-4692. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known) :___K 023070_____

Device Name :__SODEM HIGH SPEED SYSTEM (PNEUMATIC)___

Indications For Use:

The Sodem High Speed System includes a pneumatic motor which allows the fixation of spindles, adapters and attachments, which operate with drills, burs and cutters for drilling, cutting and sculpting hard tissue and bone for different applications and surgeries.

The system is intended for use in Ear Nose and Throat (plastic reconstructive surgery) applications.

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

Concurrence of CDRH, Office Of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR

Over-The Counter Use_____
(optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023070