K012453

OCT 22 2001

510(k) SUMMARY
FOR
SODEM HIGH SPEED SYSTEM (ELECTRIC)
(GENERAL ORTHOPEDIC & GENERAL PLASTIC SURGERY)

3. PREDICATE DEVICES

The Sodem High Speed System (Electric) claims equivalence to the following systems:

- Stryker: Total Performance System (TPS) (**K943589**)
- Linvatec: E9000/Advantage (**K990524 / K002523**)

4. DEVICE DESCRIPTION

The Sodem High Speed System (Electric) is a complete system including:

- two motors (*a Skull Perforator motor** and a High Speed motor),
- a foot pedal,
- a console allowing to connect the motors and to select their max. operating speed,
- dedicated wires to connect the motors, the foot pedal and the console,
- attachments/spindles,
- drills, burs and cutters

** This 510(k) doesn't deal with the skull perforator motor because we have submitted a separate 510(k) for neuro/spine applications.*

The motor is to be attached to the Sodem High Speed console and is operated with a foot pedal.

The Sodem High Speed System (Electric) is an electrical system developed in conformity with the norms IEC 60601 and UL 2601.

The Sodem High Speed System (Electric) is very similar in terms of use and technological characteristics to products currently on the market (TPS from Stryker and E9000 / Advantage from Linvatec).

Also, the Sodem High Speed System (Electric) is equivalent in terms of use with the Sodem High Speed System (Pneumatic) already submitted (K954717).

5. INTENDED USE

The Sodem High Speed motor allows the fixation of spindles, which operate with drills, burs and cutters for drilling, cutting and sculpting hard tissue and bone (knee, ankle, hand, foot, facial and maxillary bones) for orthopedics and general plastic surgery.

Motor, attachments and cutting tools are for use in general orthopedics and general plastic surgery.

6. BASIS FOR CLAIM OF SUBSTANTIAL EQUIVALENCE

The Sodem High Speed System (Electric) claims substantial equivalence to other currently marketed high-speed electric power systems. This claim is based on equivalence in:

Intended use
The Sodem High Speed System (Electric) and predicate electric instruments share the same clinical applications and intended used (orthopedics and general plastic surgery).

Materials
Patient contact materials for all systems consist of surgical stainless steel.

Sterility Status
All systems are supplied non sterile except burs and drills (special 510k N° K94175), 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

- **Console**

  All cited systems are operated using an electrical power console. Console allows to select motors and to choose operating speed. All console provide one or more connection for several hand pieces/motors (ex E9000 of Linvatec one connection for 14 hand pieces, TPS of Stryker 3 connections for approximately 10 hand pieces). Difference between Sodem console and other currently marketed consoles is that Sodem console has two specific connection (one for High Speed Motor, and one for *Skull Perforator Motor*, an inversion is not possible).

- **Accessories**

The Sodem High Speed System (Electric) 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.

Some hand pieces are designed with a terminal angle (nose piece). The Sodem and Stryker systems have an angled nose. The Linvatec E9000 / Advantage systems have an integral angling capability from straight to 20 degrees with a twist of the collet. All systems feature to ability to change burs and spindles without the need for a wrench.

- **Electrical power**

All cited systems are operated using an electrical power source controlled by a foot pedal. For all systems, users can choose maximum operating speed on the console and with the foot pedal increase or reduce speed until maximum speed selected.

The nominal power output of the Sodem High Speed System is identical or substantially equivalent to the other commercially available electrical motors (Linvatec, Stryker). The maximum drill speed of the Sodem High Speed System (Electric) is adjustable with the console from 0-80'000 rpm, the drill speed of the E9000 / Advantage system of Linvatec is adjustable with the console from 0-80'000 rpm, the drill speed of the TPS of Stryker is adjustable with the console from 0-75'000 rpm.

Based on the above comparison, SodemSystems believes that the Sodem High Speed System (Electric) is substantially equivalent to the systems cited, that any differences between the Sodem High Speed System (Electric) 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

OCT 22 2001

Ms. Carole Burnier
Quality and Regulatory Affairs Manager
Sodem Systems
110, ch. du-Pont du-Centenaire
CH - 1228
Geneva,
Switzerland

Re: K012453
Trade Name: Sodem Systems
Regulation Number: 882.4360, 882.4310
Regulation Name: Electric cranial drill motor
Powered simple cranial drills, burrs, trephines and accessories
Regulatory Class: Class II
Product Code: HBC, HBE
Dated: July 27, 2001
Received: August 1, 2001

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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,

Susan Walker, MD

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012453

Device Name: SODEM HIGH SPEED SYSTEM (ELECTRIC)

Indications For Use:

The Sodem High Speed motor allows the fixation of spindles, which operate with drills, burs and cutters for drilling, cutting and sculpting hard tissue and bone (knee, ankle, hand, foot, facial and maxillary bones) for orthopedics and general plastic surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012453