DEC 27 1999

K993851

510(k) SUMMARY
FOR
SODEM PERFORATOR DRIVE

1053

1 APPLICANT

sodemsystems
Sodem Diffusion SA
110, ch. Du Pont du
Centenaire
CH-1228 Geneva, Switzerland

Contact Person :	Daniel BACCINO
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

2 DEVICE NAME

Trade Name :	Sodem Perforator Drive
Classification Name :	Pneumatic Cranial Drill Motor
Common / Usual Name :	Surgical drill

3 PREDICATE DEVICES

The Sodem Perforator Drive claims equivalence to the following systems:

- Sodem Power System (K935567)
- Sodem High Speed System (K954717)

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4 DEVICE DESCRIPTION

The Sodem Perforator Drive PN 3510 is made out of the combination of 2 components from the Sodem Power System.
the Pneumatic motor currently used as part of the Sodem Power System and a Hudson Adapter.

Sodem is not manufacturing "Cranial Perforator attachment".

The technological characteristics of the Sodem Perforator Drive are similar to the pneumatic handpiece from the Sodem Power System.

The safety device (disengagement of rotational movement of the "cranial perforator attachment"after relevant perforation of skull) is exclusively dependent of this attachment (not the motor).

This safety device is functional so far the speed range is being respected.

The speed range is indicated on the instructions for use of the manufacturer(s) of the "cranial perforator attachments" and our perforator drive motor is falling within recommended range of operation.

5 INTENDED USE

The Sodem Perforator Drive is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits on a patien's skull. The system is intended for use in neurosurgery.

6 BASIS FOR CLAIM OF SUBSTANTIAL EQUIVALENCE

Sodemsystems claims substantial equivalence to other Perforator Motors. This claim is based on equivalence in:

Intended use
The intended use of the Sodem Perforator Drive is identical to that of the Sodem High Speed System as cited above.

Materials
The materials of the Sodem Perforator Drive are not in direct patient contact and similar with the Sodem Power System.

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Sterility Status
The Sodem Perforator Drive is, like the cited predicate systems, provided non-sterile, require decontamination after use, and resterilzation by the user facility.

Pneumatic power
Systems operate using compressed air or nitrogen. Power to the Sodem Perforator Drive is adjustable from 0-950. Range is comparable for the cited predicate device, Sodem Power System.

Operational Principles
The Sodem Perforator Drive and cited predicate system use the same operational principles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 1999

Mr. Daniel Baccino
Quality and Regulatory Affairs Director
Sodemsystems
Sodem diffusion s.a.
110, ch. du Pont-du-Centenaire
CH 1228 Geneva
Switzerland

Re: K993851
Trade Name: Sodem Perforator Drive
Regulatory Class: II
Product Code: HBB
Dated: November 9, 1999
Received: November 12, 1999

Dear Mr. Baccino:

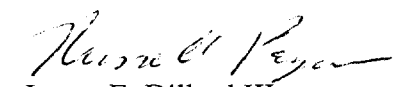
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) PREMARKET NOTIFICATION
For the Sodem Perforator Drive

Indications for Use Statement

510(k) Number: K993851

Device Name: *Perforator Drive*

Indication for Use :
The Sodem Perforator Drive is intended for use in neurosurgery.

(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)

Over-The-Counter Use _____

vision Sign-Off)
ision of General Restorative Devices
O(k) Number K993851