MAR 18 1998

k974726

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Trade (proprietary) Name

Subdural Drainage Catheter Kit

2. Common/Classification Name

Drainage Catheter/Central Nervous System (CNS) Fluid Shunt and Components

3. Applicant's Name and Address

Elekta Implants S.A.
Parc de Sophia Antipolis
Route des Dolines 2905
F-06921 Sophia Antipolis, France

4. Classification

The kit includes devices classified as Class II (21 CFR 882.5550 and 21 CFR 882.4300).

5. Predicate Devices

Cordis Straight Ventricular Catheter with oval holes
P.S. Medical Surgical Drain
Cordis Orbis Sigma® Valve
Cordis Polypropylene Burr Hole Reservoirs
Cordis Ventricular Antechamber
Cordis Right Angle Catheter Guide
Cordis CSF Reservoir

6. Performance Standards

No applicable performance standards have been established by FDA under Section 514 of the Food, Drug and Cosmetic Act.

7. Intended Use and Device Description

The Subdural Drainage Catheter is intended for drainage of extraventricular fluid collections, ***such as hygromas and chronic hematomas,*** into an external drainage system, (such as the Suction Reservoir or the EDS or IDS Systems from Elekta) or an implanted catheter communicating with an appropriate drainage site (i.e., peritoneum).

The patient's clinical pathology dictates whether the Subdural Drainage Catheter is connected to an internal or external drainage system.

The catheter is manufactured from silicone elastomer (with barium sulfate) equivalent to those of other Cordis catheters and CNS fluid shunt systems and components. The distal catheter ends in a hollow, ovoid-shaped structure ("cage") with slit-like openings. For implantation, a stylet is passed through the proximal end of the catheter, and is pushed against the interior cage bottom. This elongates the cage and allows the catheter to be passed through a 5 mm diameter burr hole. When the distal tip is appropriately placed, the stylet is removed and the catheter tip returns to its cage-like appearance.

8. Biocompatibility

The materials used to manufacture the Subdural Drainage Catheter have been subjected to biocompatibility testing. The tests reveal that the materials used are safe for their intended use.

9. Summary of Substantial Equivalence[1]:

The indications and contraindications of the Subdural Drainage Catheter Kit are equivalent to those of the predicate devices and their accessories. The design, materials, manufacturing methods and specifications of the Subdural Drainage Catheter are similar to those of the predicate Cordis Ventricular Catheters and do not raise any new issues relating to safety and effectiveness for its intended use.

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[1]Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "*. . . a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without premarket approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits.*" 42 Fed. Reg. 42,520 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

Ms. Barbara Ramseyer
Elekta Implants
6011 Cellini Street
Coral Gables, Florida 33146

Re: K974726
Trade Name: Subdural Drainage Catheter Kit,
Subdural Catheter
Regulatory Class: II
Product Code: JXG
Dated: December 15, 1997
Received: December 18, 1997

Dear Ms. Ramseyer:

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,

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

Enclosure

Elekta Subdural Drainage Catheter Kit

510(k) Number: K974726

Device Name: **Elekta Subdural Drainage Catheter Kit**

Indications for Use:

The Subdural Drainage Catheter Kit is intended for drainage of extraventricular fluid collections, ***such as hygromas and chronic hematomas,*** into an external drainage system (such as the Suction Reservoir or the EDS or IDS Systems from Elekta) or an implanted catheter communicating with an appropriate drainage site. The patient's clinical pathology dictates whether the Subdural Drainage Catheter is connected to an internal or external drainage system.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription (Per CFR 801.109)	or	Over the Counter Use (Optional Format 1-2-96)
✓		

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974726