FEB -6 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

K971799

1. Trade (proprietary) Name

Precision Flow™ OSV II

2. Common/Classification Name

Central Nervous System (CNS) Fluid Shunt System

3. Applicant's Name and Address

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

4. Classification

This device is classified as Class II (21 CFR 882.5550).

5. Predicate Devices

Cordis Orbis Sigma® Valve
Cordis Omnishunt® System
Cordis Polypropylene Connectors
Cordis Ventricular Antechamber
Cordis Straight or Finned Ventricular Catheters (with radiopaque dots)

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 Precision Flow OSV II intended use is the same as the Orbis Sigma Valve: it is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

The Orbis Sigma Valve and the Precision Flow OSV II are both variable resistance valves that maintain a drainage rate close to the rate of CSF secretion (~ 20 ml/h) within the physiological range of intracranial pressure. The mechanism incorporates a safety pressure relief mode to prevent accidental intracranial hypertension.

The principle of operation consists of a flow restricting diaphragm, a seat, and a notched pin. The diaphragm, held between two polysulfone parts of the casing, reacts to variations in pressure. A synthetic ruby seat is inserted into the center of the diaphragm. The clearance between the seat aperture and the notched synthetic ruby pin varies depending on seat movements along the pin as pressure varies (see Section 4). Precision Flow OSV II and Orbis Sigma Valve are characterized by the same three stages of operation, that are defined below :

Stage I - Low Differential Pressure (DP)
This stage begins when the flow rate through the valve reaches 5ml/hr (DP will be between 30 and 80 mm H_20). The valve remains in Stage I with CSF flow rates up to 18 ml/hr (DP will be between 40 and 120 mm H_20).

Stage II - Flow Regulation
When the DP increases, the valve operates as a variable resistance flow regulator. At DP ranges between 120 and 300 mm H_20, the valve restricts flow between 18 and 30 ml/hr.

Stage III - Pressure Relief Mode
Should the intraventricular pressure (IVP) elevate abruptly, the shunt operates in a rapid flow rate mode to facilitate IVP normalization. The valve then reverts to Stage II or I, depending upon conditions.

The concept of the flow regulation linked to the OSV hydrodynamic specifications has been developed by Pr C. Sainte Rose M.D. (Sainte Rose, Hooven MD, Hirsch JF. A new approach in the treatment of hydrocephalus. J Neurosurg.66:213-226, 1987- attached to this section).
This concept has been validated by clinical studies and use over more than seven years (Refer to the OSV Premarket Notification K913636 and Post-Market Surveillance report dated June 3, 1994).

8. Biocompatibility

The biocompatibility of the materials used in the manufacture of the Precision Flow OSV II has been documented in the Premarket Notifications of the Orbis Sigma Valve, the Cordis Ventricular Antechamber and the Cordis Straight or Finned Ventricular Catheters. No new issues related to biocompatibility are raised.

9. Summary of Substantial Equivalence[1]:

The indications, contraindications, operating principle, and performance specifications of the Precision Flow OSV II are identical to those of the predicate Orbis Sigma Valve. The design, materials, manufacturing methods and specifications of the Precision Flow OSV II are equivalent to those of the predicate devices and do not raise any new issues relating to safety and effectiveness for its intended use.

[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

FEB - 6 1998

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

Re: K971799
Trade Name: Precision Flow OSV II
Regulatory Class: II
Product Code: JXG
Dated: December 19, 1997
Received: December 23, 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.

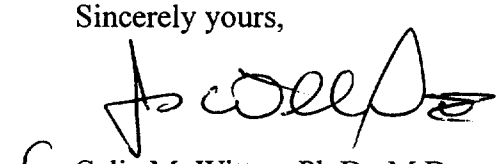
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , 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

Precision Flow OSV II

510(k) Number: K971799

Device Name: Precision Flow ™OSV II

Indications for Use:

The Precision Flow OSV II is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971799

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

Prescription Use X
(Per 21 CFR 801.109)