

SECTION 2 - SUMMARY AND CERTIFICATION

DEC 20 1996

**Summary of Safety and Effectiveness
Cordis Cyst Puncture Catheter Kit**

(Pursuant to Section 513(I) of the Federal Food, Drug, and Cosmetic Act)

I. General Information:

Cordis Sharp-ended Stylet

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|-------------------------|---------------------------|
| Classification Name: | Microsurgical instrument |
| Common/Usual Name: | Puncture Cannula |
| Trade/Proprietary Name: | Cordis Sharp-ended Stylet |

Cordis Blunt-ended Stylet

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|-------------------------|-------------------------------|
| Classification Name: | Shunt implantation instrument |
| Common/Usual Name: | Stylet |
| Trade/Proprietary Name: | Cordis Blunt-ended Stylet |

Cordis Cyst Puncture Catheter

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|-------------------------|-------------------------------|
| Classification Name: | Ventricular Catheter |
| Common/Unusual Name: | Catheter |
| Trade/Proprietary Name: | Cordis Cyst Puncture Catheter |

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| Applicant's Name and Address: | Cordis Corporation 14201 NW 60th Avenue Miami, FL 33014 |
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II. Name of predicate device(s):

| Component | Predicate Device |
|-------------------------|--|
| Sharp-ended stylet: | Elekta Blacklund Needle (Preamendments). |
| Blunt-ended stylet: | Cordis Ventricular Catheter Stylet (Preamendments). Cordis Ventricular Catheter Introducer (Orbis-Sigma Valve (K913636)). |
| Cyst Puncture Catheter: | Cordis Ventricular Catheter with Enlarged Holes (K914995). |

III. Classification:

When used alone as a cyst puncture needle, the Cordis Cyst Puncture Stylet is a Microsurgical Instrument (Class I - 21 CFR 882.4525). Neurosurgical shunt system instruments are Class I (21 CFR 882.4545). Ventricular Catheters are Class II (21 CFR 882.4100).

IV. Performance Standards:

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

V. Intended Use and Device Description:

The Cordis Cyst Puncture Catheter Kit is intended to facilitate puncturing thick-walled or mobile intracranial cysts, allowing insertion of a ventricular catheter for cyst drainage.

VI. Summary of Substantial Equivalence¹:

Indications for use: The Cordis Cyst Puncture Catheter Kit is used to puncture and drain thick-walled or mobile intracranial cysts.

System Description: The Cordis Cyst Puncture Catheter kit consists of a ventricular catheter with enlarged holes whose distal tip has been modified. The modification allows the sharp-ended stylet to be inserted through and locked into the distal tip. This facilitates cyst puncture. The kit also includes sharp- and blunt-ended stylets to facilitate catheter placement. The catheter is manufactured from silicone elastomer made radiopaque with barium sulfate (see Section 5 for Biocompatibility Assessment and Appendix III for Radiopacity Validation Data).

Standard stereotactic techniques are used to localize the cyst entry point. The blunt-ended stylet, included in the kit, inserted into the catheter to approach the cyst wall. After contacting the cyst wall, the blunt-ended stylet is exchanged for the sharp-ended stylet. The sharp-ended stylet is pushed through the small hole in the distal catheter tip until the flange is seated against the molded shelf of the catheter. The stylet/catheter assembly is then advanced until the sharp-ended stylet punctures the cyst wall. The ventricular catheter can

¹Any 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 pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patient 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 pre-market approval or classification. This determination is not intended to have any bearing whatever on resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).

then be advanced into the lumen of the cyst. The stylet is then withdrawn, leaving the catheter in place to drain the cyst.

The indications for the Cordis Sharp- and Blunt-ended Stylets and Cyst Puncture Catheter are similar to those for the predicate devices.

Design, Materials, Manufacturing Methods and Specifications:

The design, materials, manufacturing methods and specifications of the components of the Cordis Cyst Puncture Catheter Kit are similar to those of the predicate devices and do not raise any new issues relating to safety and effectiveness for their intended use. Thus, Cordis considers the Cordis Cyst Puncture Catheter Kit to be equivalent to predicate devices.