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SECTION - 2
SUMMARY AND CERTIFICATION
(Pursuant to Section 513(I) of the Federal Food, Drug, and Cosmetic Act)

1. Trade (proprietary) Name

Cordis Ventricular Antechamber (VA)

2. Common/Classification Name

Ventricular Antechamber/Central nervous system fluid shunt and components

3. Applicant's Name and Address

Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700

4. Classification

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

5. Predicate Devices

Cordis Orbis Sigma Valve (OSV)
Cordis Polypropylene Burr Hole Reservoirs
Cordis CSF Reservoir
Cordis Right Angle Guide
Cordis Right Angle Catheter
Cordis Polypropylene Straight, "Y" & "T" Connectors

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 Cordis Ventricular Antechamber (VA) is a component of a central nervous system (CNS) fluid shunt. It connects the ventricular catheter to the valve's integral tubing. In this configuration, it serves to conduct cerebrospinal fluid (CSF) from this catheter to the valve. It may also be used with a ventricular catheter alone. In either configuration, the VA facilitates CSF sampling. The Cordis Ventricular Antechamber is manufactured from silicone elastomer (with/without barium sulfate), polysulfone and polypropylene impregnated with barium sulfate.

8. Biocompatibility

The materials used to manufacture the Cordis Ventricular Antechamber have been subjected to biocompatibility testing and are safe for their intended use.

9. Summary of Substantial Equivalence[1]:

The indications and contraindications of the Cordis Ventricular Antechamber are the same as those for the predicate Cordis antechambers. The design, materials, manufacturing methods and specifications of the Cordis Ventricular Antechamber are equivalent to those of the predicate devices 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).