K963839

ATTACHMENT - 1

SUMMARY OF SAFETY AND EFFECTIVENESS

a. Trade (proprietary) Name

Cordis Suction Reservoir Kit

DEC 12 1996

b. Common/Classification Name

Suction reservoir/Nonpowered, single patient, portable suction apparatus.

c. Applicant's Name and Address

Cordis Corporation
14201 NW 60th Avenue
Miami Lakes, FL 33014

d. Classification

This device is classified as Class I (21 CFR 878.4680).

e. Predicate Devices

Sil-Med Suction Reservoir
Cordis Integral Drainage/Ventricular/Lumbar Drainage Sets

f. Performance Standards

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

g. Intended Use and Device Description

The Cordis Suction Reservoir Kit is intended to be used with the Cordis Subdural Drainage Catheter for drainage of extraventricular fluid collections. The kit consists of a Suction Reservoir and an extension tubing with an integrated male Luer connector. The Suction Reservoir has a 100 cc capacity with graduated markers every 25 cc allowing measurement of fluid collections. It also incorporates an anti-reflux valve to prevent backflow. The Suction Reservoir provides consistent negative pressure while returning to its original shape and volume.

h. Biocompatibility

No new issues of biocompatibility are raised. The Suction Reservoir was cleared for a wide variety of applications in post-operative drainage procedures, including neurosurgery applications. The extension line was cleared for a similar application (cerebrospinal fluid drainage, sampling and collection).

I. Summary of Substantial Equivalence[1]:

The indications and contraindications of the Cordis Suction Reservoir Kit are included in those of the predicates. The design, materials, manufacturing methods and specifications of the Cordis Suction Reservoir Kit 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).