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Appendix III

K960159

Summary of Safety and Effectiveness

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

I. General Information

Classification Name:

Central nervous system fluid shunt system component

Common/Usual Name:

Ventricular Catheter

Proprietary Name:

Cordis Straight or Finned Ventricular Catheter (with radiopaque dots)

Applicants Name and Address:

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

II. Name of predicate device(s):

Cordis Straight Ventricular Catheter (Cat. No. 951-102)
Cordis Finned Ventricular Catheter (Cat. No. 951-101)

Heyer-Schulte In-Line Valve System

Heyer-Schulte Portnoy Ventricular Catheter

III. Classification:

Central nervous system fluid shunts and components were reviewed by the Neurological Devices Classification Panel and placed in Class II (21 CFR 882.5550).

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 Ventricular Catheter (with radiopaque dots) is a component of an implanted cerebrospinal fluid shunt system. It serves to transmit cerebrospinal fluid (CSF) to the valve mechanism from the cerebral ventricles or from extraventricular structures. It is a component sold alone for use in implanted hydrocephalus shunt systems or in kits containing all components for hydrocephalus shunt system implantation. Indications and contraindications are the same as the Cordis Ventricular Catheters which have been sold by Cordis for over 20 years. Catheters are manufactured from the same materials currently used in other Cordis catheters with the exception of the addition of tantalum in the dot. The Cordis Ventricular Catheter (with radiopaque dots) is manufactured from silicone elastomer made radiopaque with barium sulfate. The radiopaque dots are formed by mixing tantalum powder in Liquid Silicone Rubber (LSR) and applying the mixture, fully coated with silicone elastomer, to the wall of a catheter to provide a means of determining the location and depth of the catheter on X-ray.

VI. Biocompatibility:

Implanted materials in contact with body tissues or body fluids are silicone elastomer with barium sulfate, and Liquid Silicone Rubber.

VII. Summary of Substantial Equivalence:

Indications: The indications and contraindications of the Cordis Ventricular Catheter (with radiopaque dots) are the same as those for the Cordis Straight or Finned Ventricular Catheters.

Design: The dimensions of the Cordis ventricular catheters (with radiopaque dots) are the same as those for predicate Cordis ventricular catheters.

Materials: The materials used in the manufacturing of the Cordis ventricular catheters (with radiopaque dots) are the same as those for the predicate Cordis ventricular catheters except for the addition of tantalum markers. Tantalum dots have been used in conjunction with the predicate Heyer-Schulte devices.

Manufacturing: The manufacturing process used in the production of Cordis ventricular catheters (with radiopaque dots) is similar to those used for predicate Cordis ventricular catheters. No new safety or effectiveness issues are raised.

Specifications: The specifications (radiopacity, pull strength, etc.) for the Cordis ventricular catheters (with radiopaque dots) are the same as for the predicate Cordis ventricular catheters.

Conclusions: The indications, design and specifications of the Cordis ventricular catheters (with radiopaque dots) are the same as the predicate Cordis ventricular catheters. The addition of radiopaque dots raise no new issues of safety or effectiveness.

Cordis thus considers the Cordis Straight or Finned Ventricular Catheters (with radiopaque dots) to be substantially equivalent to the predicate Cordis and Heyer-Schulte ventricular catheters with radiopaque markings.