K102961

510(k) SUMMARY

FEB 18 2011

Company Name:	Codman & Shurtleff, Inc.
Company Address:	325 Paramount Drive Raynham, MA 02767-0350
Phone:	(508) 828-3421
Fax:	(508) 828-2777
Contact Person:	Jocelyn Raposo, Senior Regulatory Affairs Specialist
Date:	October 4, 2010
Name of the Device:	Central Nervous System Fluid Shunt and Components
Propriety / Trade Name:	CODMAN® HOLTER® In-Line Shunt Filter, Hoffman Design CODMAN® HOLTER® Cerebral Catheter-Reservoir, LeRoy Design CODMAN® ACCU-FLO® Straight Connector, Stainless Steel CODMAN® MEDOS® Straight Connector CODMAN® HOLTER® Type A Fixation and Joining Connector CODMAN® HOLTER® Type B Fixation and Joining Connector CODMAN® ACCU-FLO® Connector, Three Way, Stainless Steel CODMAN® HOLTER® RICKHAM® Reservoir CODMAN® HOLTER® SALMON™-RICKHAM® Reservoir CODMAN® ACCU-FLO® Right Angle Connector, Stainless Steel CODMAN® MEDOS® Right Angle Connector CODMAN® HOLTER® SELKER Reservoir CODMAN® ACCU-FLO® Straight Connector, Plastic CODMAN® ACCU-FLO® Connector, Three Way, Plastic CODMAN® ACCU-FLO® Right Angle Connector, Plastic
Common Name:	Hydrocephalus Shunt System Accessories
Classification:	Class II (JXG) per 21 CFR § 882.5550 Central Nervous System Fluid Shunt and Components
Legally Marketed Device:	Preamendment – CODMAN® HOLTER® In-Line Shunt Filter, Hoffman Design Preamendment – CODMAN® HOLTER® Cerebral Catheter-Reservoir, LeRoy Design Preamendment – CODMAN® ACCU-FLO® Straight Connectors

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K102961

K944222 - CODMAN® MEDOS® Straight Connector
Preamendment – CODMAN® HOLTER® Type A Fixation and Joining Connector
Preamendment – CODMAN® HOLTER® Type B Fixation and Joining Connector
Preamendment – CODMAN® ACCU-FLO® Connector, Three Way
Preamendment – CODMAN® HOLTER® RICKHAM® Reservoir
Preamendment - CODMAN® HOLTER® SALMON™-RICKHAM® Reservoir
Preamendment – CODMAN® ACCU-FLO® Right Angle Connectors
K944222 - CODMAN® MEDOS® Right Angle Connector
Preamendment - CODMAN® HOLTER® SELKER Reservoir
K973774 - CODMAN® ACCU-FLO® Straight Connector, Plastic
K973774 - CODMAN® ACCU-FLO® Connector, Three Way, Plastic
K973774 - CODMAN® ACCU-FLO® Right Angle Connector, Plastic

Device Description: The hydrocephalus accessories consist of connectors, reservoirs, and a filter. The connectors are made of stainless steel or plastic and are used in the joining and fixation of silicone rubber tubing. The reservoirs are made of silicone, stainless steel, and/or plastic and are used for the purpose of diagnostic studies or therapeutic drug administration. The filter is made of stainless steel and silicone and is used to filter particles.

Intended Use: The hydrocephalus accessories are intended for use with Codman's Hydrocephalus Shunt Systems.

Summary of technological characteristics of the proposed to the predicate device:

No new technological characteristics are being introduced in comparison to the predicate devices. The technological characteristics of the devices remain the same. No changes are being made to the device design, materials, performance, or intended use.

Performance Data: Bench testing was performed according to the following MRI standards: ASTM F 2052, ASTM F 2213, ASTM F 2119, and ASTM F 2182. The test results demonstrate that there is no added risk to the patient when exposed to a 3 Tesla MR system. The devices that are made of silicone and plastic were evaluated and determined to be MR Safe since they do not contain metallic or conducting materials. The

results and evaluation conclude that the devices are MR Conditional or MR Safe in 3-Tesla Magnetic Resonance Imaging (MRI) systems according to ASTM F 2503 and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc.
c/o Ms. Jocelyn Raposo
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767-0350

FEB 18 2011

Re: K102961
Trade/Device Name: CODMAN® HOLTER® In-Line Shunt Filter, Hoffman Design
CODMAN® HOLTER® Cerebral Catheter-Reservoir, LeRoy Design
CODMAN® ACCU-FLO® Straight Connector, Stainless Steel
CODMAN® MEDOS® Straight Connector
CODMAN® HOLTER® Type A Fixation and Joining Connector
CODMAN® HOLTER® Type B Fixation and Joining Connector
CODMAN® ACCU-FLO® Connector, Three Way, Stainless Steel
CODMAN® HOLTER® RICKHAM® Reservoir
CODMAN® HOLTER® SALMON™-RICKMAN® Reservoir
CODMAN® ACCU-FLO® Right Angle Connector, Stainless Steel
CODMAN® MEDOS® Right Angle Connector
CODMAN® HOLTER® SELKER Reservoir
CODMAN® ACCU-FLO® Straight Connector, Plastic
CODMAN® ACCU-FLO® Connector, Three Way, Plastic
CODMAN® ACCU-FLO® Right Angle Connector, Plastic
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: January 18, 2011
Received: January 19, 2011

Dear Ms. Raposo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tessia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® MEDOS® Straight Connector
CODMAN® MEDOS® Right Angle Connector

Indications for Use:

The Codman-Medos Connector is for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® HOLTER® Type A Fixation and Joining Connector

Indications for Use:

The Type A Fixation and Joining Connector is indicated for use in the joining and fixation of 1.2 mm nominal I.D. silicone rubber tubing with nonabsorbable sutures in a surgical application.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® HOLTER® Type B Fixation and Joining Connector

Indications for Use:

The Type B Fixation and Joining Connector is indicated for use in the joining and fixation of 0.8 mm nominal I.D. silicone rubber tubing to 1.2 mm nominal I.D. silicone rubber tubing, and specifically, catalog no. 82-1672, with nonabsorbable sutures in a surgical application.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® HOLTER® SELKER Reservoir
CODMAN® HOLTER® RICKHAM® Reservoir
CODMAN® HOLTER® SALMON™-RICKHAM® Reservoir

Indications for Use:

The Ventriculostomy Reservoir Set is indicated for use to gain access to the cerebral ventricles or other intracranial cavities for the purpose of diagnostic studies or therapeutic drug administration with or without a shunting device. When used with the shunting device, the ventriculostomy reservoir is also indicated for use as the proximal fluid pathway.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® ACCU-FLO® Connector, Three Way (Stainless Steel and Plastic)

Indications for Use:

The ACCU-FLO Three Way Connector can be utilized as a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the right atrium of the heart or the peritoneal cavity, providing they are used in the joining and fixation of approximately 1.3 mm nominal I.D. silicone rubber tubing with nonabsorbable sutures in a surgical application.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® ACCU-FLO® Straight Connectors (Stainless Steel and Plastic)
CODMAN® ACCU-FLO® Right Angle Connectors (Stainless Steel and Plastic)

Indications for Use:

The ACCU-FLO Connectors can be utilized as a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the right atrium of the heart or the peritoneal cavity, providing they are used in the joining and fixation of approximately 1.3 mm nominal I.D. silicone rubber tubing with nonabsorbable sutures in a surgical application.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® HOLTER® Cerebral Catheter Reservoir, Leroy Design

Indications for Use:

The Cerebral Catheter-Reservoir is indicated for use as a component of a shunting system to gain access to the cerebral ventricles or other intracranial cavities for the purpose of diagnostic studies, therapeutic drug administration, or the diversion of fluid.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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510(k) Number K102961

INDICATIONS FOR USE

510(k) Number (if known): K102961

Device Name:

CODMAN® HOLTER® In-Line Shunt Filter, Hoffman Design

Indications for Use:

The In-Line Shunt Filter is indicated for use to filter particles that are larger than approximately 3.9 microns when neoplasm is suspected and when shunting is the procedure of choice in the treatment of hydrocephalus.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

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510(k) Number K102961