NOV 18 2011

510(k) SUMMARY
Medtronic ARES™ Antibiotic Impregnated Catheters
K110560

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Medtronic Neurosurgery
Address	125 Cremona Drive Goleta, CA 93117-5503 USA
Phone number	805-571-8400
Fax number	805-571-8480
Establishment Registration Number	2021898
Name of contact person	Jeffrey Henderson
Date prepared	November 17, 2011
Name of device	
Trade or proprietary name	Medtronic ARES™ Antibiotic-Impregnated Catheter
Common or usual name	Hydrocephalus Catheter
Classification name	Shunt, Central Nervous System and Components
Classification	Class II
Panel	Neurological
Regulation	21 CFR §882.5550
Product Code(s)	JXG
Legally marketed device(s) to which equivalence is claimed	Johnson & Johnson (Codman & Shurtleff) BACTISEAL® Catheter (K003322)
Reason for 510(k) submission	New device
Device description	The Medtronic ARES™ Antibiotic-Impregnated Catheters are manufactured using barium sulfate-filled silicone elastomer and are impregnated with clindamycin hydrochloride and rifampicin. **ARES Antibiotic-Impregnated Ventricular Catheter** The ARES ventricular catheter measures 23 cm in length, 0.13 cm in inner diameter, and 0.25 cm in outer diameter. Lengths are marked in 1 cm intervals starting from 3 cm to 15 cm from the catheter tip, thus enabling the surgeon to gauge the depth of penetration of the catheter into the lateral ventricle. The proximal end of the catheter has 32 flow holes—four lines of eight holes spaced at 90° intervals

	around the catheter circumference. Components supplied with the ARES Ventricular Catheter include a pre-loaded stainless steel stylet and a Right Angle Clip, which is included to facilitate placement and use of the ventricular catheter. **ARES Antibiotic-Impregnated Peritoneal Catheter** The ARES peritoneal catheter measures 120 cm in length, 0.13 cm in inner diameter, and 0.25 cm in outer diameter. There are no length markers or wall slits on the catheter, and the tip is open ended. The catheter may be trimmed to the proper length.
Intended use of the device	The Medtronic ARES™ Antibiotic-Impregnated Catheters are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.
Indications for use	The Medtronic ARES™ Antibiotic-Impregnated Catheters are intended for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

Summary of the technological characteristics of the device compared to the predicate device

The Medtronic ARES™ Antibiotic-Impregnated catheter is substantially equivalent in device description, function, principle of operation, and basic composition to the BACTISEAL® predicate device. The ARES and BACTISEAL devices characteristics are summarized below.

Characteristic	New Device [Medtronic ARES™ Antibiotic-Impregnated Catheters]	Predicate [BACTISEAL® Catheter, K003322]
Catheter Body Material	$BaSO_4$ filled silicone elastomer	$BaSO_4$ filled silicone elastomer
Drugs Formulation	0.054 weight % rifampicin 0.150 weight % clindamycin hydrochloride	0.054 weight % rifampicin 0.150 weight % clindamycin hydrochloride
Catheter Body Dimensions	Ventricular: 0.050" ID x 0.100" OD Peritoneal: 0.050" ID x 0.100" OD	Ventricular: 0.055" ID x 0.106" OD or 0.050" ID x 0.100" OD Peritoneal: 0.039" ID x 0.0866" OD or 0.050" ID x 0.100" OD
Catheter Length	Ventricular: 23 cm Peritoneal: 120 cm	Ventricular: 14, 15, or 23 cm Peritoneal: 120 cm
Length Markers	Ventricular: numerical length markers Peritoneal: None	Ventricular: 1 dot at 10 cm & 2 dots at 15 cm Peritoneal: None
Tip Configuration	Ventricular: Bullet shape with 32 inlet holes (4 rows of 8 holes) Peritoneal: Open end, no slits	Ventricular: Bullet shape with 24 inlet holes (3 rows of 8 holes) Peritoneal: Open end, no slits

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary

The ARES™ Antibiotic-Impregnated Catheters have been designed and tested to meet the requirements of voluntary standards and FDA guidance documents applicable to the subject and predicate devices. Results of the non-clinical testing support the conclusion of substantial equivalence to the ARES™ Antibiotic-Impregnated Catheters to the predicate devices.

Characteristic	Standard/Test/FDA Guidance	Results Summary
Performance Testing	Performance testing was performed according to ISO 7197: Neurosurgical implants - Sterile, single use hydrocephalus shunts and components and ASTM 647-94 Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	The ARES Antibiotic-Impregnated Catheters have been designed and successfully tested to meet the applicable requirements outlined in ISO 7197 and ASTM 647-94
Sterilization Testing	Sterilization testing was performed according to ISO 17665: Sterilization of health care products – Moist heat	Sterilization of ARES™ Antibiotic-Impregnated Catheters is validated using the Half Cycle method as outlined in ISO 17665 to a sterility assurance level (SAL) of 10^{-6}.
Pyrogen Testing	Pyrogen testing was performed according to ANSI/AAMI/ST72 Bacterial endotoxins – Test methodologies, routine monitoring and alternatives to batch testing	ARES Antibiotic-Impregnated Catheters conform to FDA standards concerning pyrogen levels for devices in contact with cerebrospinal fluid. Utilizing the Kinetic-Chromogenic LAL method, the product meets a 2.15 EU/device specification.

Biocompatibility Test Summary

For purposes of biocompatibility testing, the Medtronic ARES™ Antibiotic-Impregnated Catheters are considered an implant device with tissue/bone contact and permanent contact duration of greater than 30 days. The selection of biocompatibility testing for Medtronic ARES™ Antibiotic-Impregnated Catheters was based on this categorization of the device, and in accordance with *ISO 10993-1:2009– Biological evaluation of medical devices-Part 1: Evaluation and testing* and the FDA Blue Book Memo, G95-1, Use of the International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

Test System	Study Results	Conclusion
Cytotoxicity – MEM Elution (ISO 10993-5)	No biological reactivity (Grade 0) was observed at 48 hours post exposure to the test article extract.	Non-cytotoxic
Sensitization – Kligman Maximization (ISO 10993-10)	The extracts of the test article elicited no reaction at the challenge (0% sensitization), following an induction phase.	Non-sensitizing
Intracutaneous Irritation/Reactivity – Intracutaneous Injection (ISO 10993-10)	All animals increased in weight and none exhibited over signs of toxicity at any observation point. The test article extract sites did not show a significantly greater biological reaction than the sites injected with the control article extract.	Non-irritant
Acute Systemic Toxicity – Systemic Injection (ISO 10993-11)	All animals increased in weight and none exhibited overt signs of toxicity at any observation point. The test article extracts did not induce a significantly greater biological reaction than the control extracts.	Non-toxic (acute)
Bacterial Reverse Mutation Study - Non-antibiotic impregnated catheter (ISO 10993-3)	DMSO and saline test article extracts were considered to be non-mutagenic to *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537 and to *Escherichia coli* tester strain WP2*uvrA*.	Non-genotoxic
Bacterial Reverse Mutation Assay – Extracts - Mock-impregnated catheter (ISO 10993-3)	DMSO and saline test article extracts were considered to be non-mutagenic to *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537 and to *Escherichia coli* tester strain WP2*uvrA*.	Non-genotoxic
In Vitro Mouse Lymphoma Assay with Extended Treatment (ISO 10993-3)	The mutant frequencies and cloning efficiencies of preparations treated with test article were within the limits defined for a negative response.	Non-genotoxic
Mouse Peripheral Blood Micronucleus Study (ISO 10993-3)	The test article extracts did not induce micronuclei in mice.	Non-genotoxic
Implantation – 13 week brain and subcutaneous implant (ISO 10993-6) & Sub-Chronic / Chronic Toxicity (ISO 10993-11)	The test article does not appear to demonstrate any systemic signs of toxicity when implanted in the brain and subcutaneous tissue of New Zealand White rabbits for a period of 13 weeks.	No local adverse event Non-toxic (sub-chronic)

K110560

Comparative Performance Information Summary			
Characteristic	Requirement	ARES	BACTISEAL
Drug release kinetics	Demonstration of antibiotics release kinetics over a 38 day period is the same for ARES and BACTISEAL	Antibiotics release kinetics measured over a 38 day period Antibiotic release rates demonstrated the same as BACTISEAL antibiotic release rates	Antibiotics release kinetics measured over a 38 day period Antibiotic release rates demonstrated the same as ARES antibiotic release rates
Zone of Inhibition Testing	Demonstration of antimicrobial activity for at least 31 days has statistically equivalent zones of inhibition for ARES and BACTISEAL	Antimicrobial activity demonstrated for at least 31 days Measured ZOIs statistically equivalent to those of BACTISEAL	Antimicrobial activity demonstrated for at least 31 days Measured ZOIs statically equivalent to those of ARES
Catheter Crush Resistance	ARES catheter mean value must not be significantly lower than control group (BACTISEAL) mean using a two sample t-test at 95% confidence	Pass	Pass
Drug Content	Clindamycin: 0.150 ± 45% Rifampicin: 0.054 ± 60%	Pass	Pass

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No prospective clinical trials were conducted in support of this Traditional 510(k).

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Medtronic Neurosurgery considers the Medtronic ARES™ Antibiotic-Impregnated Catheters to be the "same" as the predicate BACTISEAL® catheters according to the definition of medical devices containing antimicrobial agents considered by FDA to be "the same" as described in FDA Draft Guidance for Industry and FDA Staff - Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents (issued July 19, 2007). The indications for use, function, implantation techniques, performance characteristics, and test standards for both devices are substantially equivalent. Medtronic Neurosurgery considers the Medtronic ARES™ Antibiotic-Impregnated Catheters to be substantially equivalent to the previously cleared Codman BACTISEAL® Catheters.

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

NOV 18 2011

Medtronic, Inc.
c/o Mr. Jeffrey Henderson
Vice President, Quality and Regulations Affairs
125 Cremona Drive
Goleta, CA 93117

Re: K110560
Trade/Device Name: Medtronic Ares™ Antibiotic-Impregnated Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: November 11, 2011
Received: November 14, 2011

Dear Mr. Henderson:

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,

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

K110560

4. Indications for Use Statement

510(k) Number (if known): To be determined

Device Name: ARES™ Antibiotic-Impregnated Catheters

Indications for Use: The Medtronic ARES™ Antibiotic-Impregnated Catheters are intended 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 ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K110560