DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 5, 2017

Codman & Shurtleff, Inc.
Yoon Hee Beatty
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K162563
Trade/Device Name: YOGA Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 5, 2016
Received: December 6, 2016

Dear Ms. Beatty:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162563

Device Name
YOGA Microcatheter

Indications for Use *(Describe)*

The YOGA Microcatheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

I. Submitter

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Tel: (305) 265-2919
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Contact Person: Yoon Hee Beatty
Date Prepared: September 12, 2016

II. Device

Table 1. Device	
Device Proprietary Name	YOGA Microcatheter
Common or Usual Name	Catheter, Percutaneous
Classification Name	Catheter, Percutaneous, Class II, 21 CFR 870.1250
Regulatory Classification	II
Product Code	DQY

III. Predicate Device

The predicate and reference devices listed in **Table 2** below are applicable to the device in this submission.

Table 2. Predicate 510(k) Clearance			
510(k) Number	**Date Cleared**	**Device Name**	**Manufacturer**
K140080	04/24/2014	ENVOY Distal Access (DA) Guiding Catheter	Codman & Shurtleff, Inc.
Reference Devices			
K092702	11/20/2009	Micrus Microcatheter, Model Courier 270 (rebranded as "PROWLER 27"Microcatheter)	Codman & Shurtleff, Inc.
K112828	10/25/2011	REVIVE Intermediate Catheter	Codman & Shurtleff, Inc.
K021591	05/22/2002	PROWLER SELECT (10, 14, and Plus) Infusion Catheters with and without pre-shaped tips	Codman & Shurtleff, Inc.

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510(k) Summary, continued

IV. Device Description

The YOGA Microcatheter is a variable stiffness, end to end braided single lumen catheter designed to access small, tortuous vasculature. The microcatheter has an outer hydrophilic coating that provides lubricity during navigation of vessels. The lubricious PTFE lined inner lumen is designed to facilitate movement of guide wires and other devices. A radiopaque marker band is provided at the catheter tip to aid fluoroscopic visualization. A luer fitting located on the proximal end of the catheter hub is used to attach accessories. A steam shaping mandrel is provided in the package.

V. Indications for Use

The YOGA Microcatheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.

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510(k) Summary, continued

VI. Comparison of Technological Characteristics with the Predicate Device

Table 3 below provides a comparison of technological characteristics of the subject and predicate devices.

Table 3. Comparison of the Subject and Predicate Device

Characteristics	Predicate Device: ENVOY DA Guiding Catheter (K140080)	This Submission: YOGA Microcatheter
Intended Use	The ENVOY Guiding Catheter is intended for use in the peripheral, coronary, and neuro vasculature for the intravascular introduction of interventional/diagnostic devices.	Same as Predicate.
Product Code	DQY	Same as Predicate
Classification	21 CFR 870.1250 – Class II	Same as Predicate
Sterilization Method	Ethylene Oxide	Same as Predicate
Sterilization Assurance Level (SAL)	10^{-6}	Same as Predicate
Length	95cm & 105cm	**150cm**[1]
Internal Diameter	0.071" (1.8mm)	**0.024", 0.028", 0.032"**[2]
Outer Diameter	6.0F (0.082"/2.0mm)	**2.4F – 3.4F**[2]
Polymers	Pebax, Vestamid, Nylon compounds	Same as Predicate[3]
Reinforcement shaft	Stainless Steel/PTFE	Same as Predicate
Marker Band Material	90% Platinum / 10% Iridium	Same as Predicate
Hub	Pebax	**Grilamid**[4]
Strain Relief	Pebax	Pebax
Packaging	Pouch and Carton	**Hoop, Pouch and Carton**[5]
Shelf Life	3 years	Same as Predicate

[1] Same as PROWLER 27 (K092702).
[2] Similar size as PROWLER 27 (K092702).
[3] Distal Tip material of ENVOY DA is not present in YOGA Microcatheter.
[4] Same as REVIVE IC (K112828).
[5] Same as PROWLER 27 (K092702) hoop and REVIVE IC (K112828) pouch and carton.

VII. Performance Data

Performance Testing - Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the predicate ENVOY DA Guiding Catheter which was cleared under K140080. The following performance data are being provided in support of the substantial equivalence determination. All testing was conducted using sampling methods as required by Codman & Shurtleff, Inc. Design Control procedures. The bench testing included the following tests:

Continued on next page

510(k) Summary, continued

VII. Performance Data, Continued

Table 4: Bench Test Summary		
Test	**Test Method Summary**	**Result**
Visual Inspection	Entire length of the catheter was inspected with a microscope	PASS: Samples met the established acceptance criteria
Catheter ID	Catheter ID was verified by inserting pre-determined ID check mandrel through the catheter	PASS: Samples met the established acceptance criteria
Catheter OD	Catheter OD was measured along the length of the catheter by using laser micrometer	PASS: Samples met the established acceptance criteria
Catheter Working Length	Catheter working length was measured with a ruler	PASS: Samples met the established acceptance criteria
Distal Tip Length	Distal Tip Length was measured using Smart Scope Video Measuring system from the distal end of the catheter to the distal end of the marker band	PASS: Samples met the established acceptance criteria
Catheter Tensile Strength	Testing was conducted using an Instron Pull Tester	PASS: Samples met the established acceptance criteria
Hub Luer Taper	Testing was conducted per ISO 594-1 and ISO 594-2	PASS: Samples met the established acceptance criteria
Air Leak testing	Testing was conducted by occluding the distal end of the catheter and using a syringe partially filled with water connected to the hub of the catheter to aspirate while observing for air leakage	PASS: Samples met the established acceptance criteria
Flow Rate (static)	Testing was conducted per ISO 10555-1	PASS: Samples met the established acceptance criteria
System Liquid Leakage	System liquid leakage was tested using a burst leak tester	PASS: Samples met the established acceptance criteria
Flow Rate (dynamic)	Testing was completed using a dynamic flow rate test fixture at 100 and 300 psi, using Saline and Omnipaque 300 as injectates	PASS: Samples met the established acceptance criteria
Burst Pressure (static)	Testing was completed by occluding the distal end of the catheter and using a hydraulic burst leak tester to apply hydrostatic pressure to the catheter	PASS: Samples met the established acceptance criteria
Lumen flush	Lumen flush was conducted by flushing the catheter and counting the particulate per USP<788>	PASS: Samples met the established acceptance criteria
Coating Integrity	Coating integrity was verified by simulated use of the catheter and counting the particulate per USP<788>	PASS: Samples met the established acceptance criteria
Delamination of PTFE Liner	Testing was completed by slicing and flattening the catheter and pulling the PTFE from the polymer material using tweezers	PASS: Samples met the established acceptance criteria
Aseptic Removal	Aseptic removal was verified by opening the pouch by peeling and allowing the product to drop on a surface simulating a sterile field	PASS: Samples met the established acceptance criteria
Steam Shaping	Steam shaping was conducted by following the Instructions for Use	PASS: Samples met the established acceptance criteria
Linear Stiffness Test	Linear Stiffness test was conducted using an Instron Pull Tester	PASS: Samples met the established acceptance criteria
Lateral Stiffness Test	Lateral stiffness was measured using the dynamic three point bend tester and a pin gage	PASS: Samples met the established acceptance criteria
Track Testing	Trackability measured the force to push each device through a representative tortuous anatomical model	PASS: Samples met the established acceptance criteria

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510(k) Summary, continued

VII. Performance Data, Continued

Performance Testing - Animal
Radiopacity testing was conducted in an *in vivo* animal model to ensure the user can visualize the distal end of the catheter under fluoroscopy.

Performance Testing - Clinical
No clinical studies were required as appropriate verification and validation of the catheter and packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Sterilization
The YOGA Microcatheter is sterilized using a validated Ethylene Oxide sterilization cycle. Based on similarities with the predicate device, the YOGA Microcatheter can be adopted into the validated sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1.

Shelf-Life Testing
The YOGA Microcatheter will have a shelf life of 3 years based on the shelf life of currently cleared products, such as ENVOY DA (K140080) and REVIVE IC (K112828). A successful 3-year shelf life has been demonstrated on the ENVOY DA and the REVIVE IC as well as the sterile barrier system. The materials, manufacturing process and designs have been leveraged for the YOGA Microcatheter. Based on the material and processing methods, it can be concluded that the successful aging testing of the ENVOY DA and the REVIVE IC as well as the sterile barrier system are applicable to the YOGA Microcatheter.

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510(k) Summary, continued

VII. Performance Data, Continued

Biocompatibility Testing

The biocompatibility testing performed on the ENVOY DA Guiding Catheter (K140080) and REVIVE Intermediate Catheter (K112828) are also applicable to the proposed YOGA Microcatheter. Additional screening tests have been completed on YOGA Microcatheter in accordance with International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process.*" and FDA Bluebook Memorandum G95-1.

Table 5: Biocompatibility

Test	Test Method	Result
In Vitro Cytotoxicity – ISO MEM Elution	ISO 10993-5	**PASS**
Guinea Pig Sensitization – ISO Maximization	ISO 10993-10	**PASS***
Intracutaneous/Irritation Reactivity – ISO Irritation Study in Rabbits	ISO 10993-10	**PASS***
Acute Systemic Toxicity – ISO Systemic Toxicity in Mice	ISO 10993-11	**PASS***
In Vitro Hemolysis (ASTM Method –Extract and Direct Contact)	ISO 10993-4 ASTM F756	**PASS**
ASTM Partial Thromboplastin Time	ISO 10993-4 ASTM F2382	**PASS***
SC5b-9 Complement Activation	ISO 10993-4	**PASS***
C3a Complement Activation	ISO 10993-4	**PASS***
Material Medicated Pyrogenicity – USP Rabbit Pyrogen	ISO 10993-11 General Chapter <151>	**PASS***
In Vivo Thromboresistance in Dogs	ISO 10993-4	**PASS***
USP Physicochemical Tests	USP <661>	**PASS***
Chemical Characterization of Extractables	ISO 10993-18	**PASS**
Toxicology Risk Assessment	ISO 10993-17	**PASS**

* Results are based on testing conducted on ENVOY DA and REVIVE IC.

Conclusion

Based upon the intended use, design, materials, function, *in vitro* testing and animal testing, it is concluded that the subject device, YOGA Microcatheter, is substantially equivalent to the predicate device, ENVOY DA Guiding Catheter, therefore, does not raise different issues of safety and effectiveness.