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

July 3, 2017

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

Re: K171653
Trade/Device Name: YOGA Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 2, 2017
Received: June 5, 2017

Dear Ms. Yoon Hee 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,

Carlos L. Pena -S FDA

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)*
K171653

Device Name
YOGA Microcatheter

Indications for Use *(Describe)*
The YOGA Microcatheter is intended for use in 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

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Tel: (305) 265-2919
Fax: (305) 265-6889

Contact Person: Yoon Hee Beatty
Date Prepared: June 2, 2017

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 device listed in **Table 2** below is applicable to the device in this submission.

Table 2. Predicate 510(k) Clearance			
510(k) Number	**Date Cleared**	**Device Name**	**Manufacturer**
K162563	01/05/2017	YOGA Microcatheter	Codman & Shurtleff, Inc.

IV. Device Description

The YOGA Microcatheter is a variable stiffness, single lumen catheter designed to access small, tortuous vasculature. The catheter shaft is composed of a variable pitch stainless steel braid with a PTFE inner liner to facilitate movement of guide wires and other devices. The exterior of the catheter shaft is covered with a polymer material, which encapsulates the stainless steel braid construction. The distal end of the catheter has a radiopaque marker band and has a hydrophilic coating to provide lubricity for navigation of vessels. The proximal end of the catheter has a hub and an ID band is placed at the distal end of the hub over a strain relief. A steam shaping mandrel is provided in the package. The two new YOGA Microcatheters are provided in back up (XB) and extra backup (XXB) configurations, i.e. a stiffer distal end to provide additional support.

V. Indications for Use

The YOGA Microcatheter is intended for use in 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: YOGA Microcatheter (K162563)**	**This Submission: YOGA 32XB and YOGA 32XXB Microcatheters**
Intended Use	The YOGA Microcatheter is intended for use in 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	150cm	Same as Predicate
Internal Diameter	0.024", 0.028", 0.032"	Same as Predicate
Outer Diameter	2.4F – 3.4F	Same as Predicate
Polymers	Pebax, Vestamid, Nylon compounds	Same as Predicate
Reinforcement shaft	Stainless Steel/PTFE	Same as Predicate
Marker Band Material	90% Platinum / 10% Iridium	Same as Predicate
Hub	Grilamid	Same as Predicate
Strain Relief	Pebax	Same as Predicate
Packaging	hoop, pouch, carton	Same as Predicate
Shelf Life	3 years	Same as Predicate

VII. Performance Data

Performance Testing - Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the predicate YOGA Microcatheter which was cleared under K162563. 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:

Table 4: Bench Test Summary		
Test	**Test Method Summary**	**Result**
Linear Stiffness Test	Linear Stiffness was measured using Instron tester, holding fixture and ruler	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
No *in vivo* testing was 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.

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 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.

Biocompatibility Testing
Based on the same materials used to manufacture the YOGA Microcatheters (K162563), it was determined that the biocompatibility data from the predicate device can be leveraged. The tests were previously completed in accordance with International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process"*, FDA Bluebook Memorandum G95-1, and FDA's Guidance Document entitled "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" issued April 23, 2013.

Conclusion
Based upon the intended use, design, materials, function, side-by-side *in-vitro* testing and packaging testing it is concluded that the subject device, YOGA Microcatheter, is substantially equivalent to the predicate device YOGA Microcatheter cleared under 510(k) K162563. Therefore, the modified YOGA Microcatheter does not raise different issues of safety and effectiveness.