DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 13, 2015

Summa Therapeutics, LLC
Richard Rush
Regulatory Affairs Consultant
257 Castro Street, #216
Mountain View, California 94041

Re: K150452
Trade/Device Name: ComboCath OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: July 17, 2015
Received: July 21, 2015

Dear Mr. Rush:

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 yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K150452

Device Name
Summa Therapeutics ComboCath(TM) OTW PTA Dilatation Catheter

Indications for Use *(Describe)*
The ComboCath™ OTW PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

February 19, 2015

To Whom It May Concern:

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) number: K150452

Date Prepared:
February 19, 2015

Applicant Information:
Summa Therapeutics, LLC
257 Castro Street, #216
Mountain View, CA 94041

Contact Person:
Richard Rush, Regulatory Affairs Consultant
Phone Number: (650) 766-9666
Fax Number: (650) 560-6383

Device Information:

Trade Name:	ComboCath™ OTW PTA Dilatation Catheter
Common Name:	Balloon Catheter
Classification:	Class II per 21 CFR 870.1250
Classification Name:	Catheter, Percutaneous
Product Code:	LIT

Physical Description:

The ComboCath™ OTW PTA Dilatation Catheter is an 0.014" (0.36mm) guidewire compatible balloon angioplasty catheter with an effective working length of 150cm. The angioplasty catheter includes a semi-compliant distal Balloon of known diameter and length when inflated to recommended pressures.

The device construction consists of a catheter shaft with two independent lumens extending along its length. One lumen is for inflation and deflation of the angioplasty balloon. The other lumen is for placement of the guidewire and injection of fluids via the catheter's Exit Holes that are positioned proximal to the Balloon.

The proximal Hub includes an Inflation Port used for inflation and deflation of the Balloon and a standard Touhy-Borst valve with a side port terminated by a Stopcock that permits injection of fluids.

The catheter includes three radiopaque markers to aid angiographic placement of the device.

Indications for Use:
The ComboCath™ OTW PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Predicate Device:
Boston Scientific (Coyote™ ES) PTA Balloon Dilatation Catheter (K111295)

The devices share similar intended use, technological characteristics, construction, and materials, as are commonly found in intravascular balloon catheters.

Substantial equivalence:
The ComboCath™ OTW PTA Dilatation Catheter's design, materials, operating principles and intended use are substantially equivalent to predicate device Boston Scientific (Coyote™ ES) PTA Balloon Dilatation Catheter (K111295).

Performance
Functional testing was conducted to support the claim of substantial equivalence and to demonstrate performance of the ComboCath™ OTW PTA Dilatation Catheter for its intended use.

Both devices were evaluated and found similar in design and materials as summarized in Table 4-1 below:

Table 4-1: Design and Materials Comparison

Characteristic	Summa Therapeutics' ComboCath™ OTW PTA Dilatation Catheter	Boston Scientific (Coyote™ ES) PTA Balloon Dilatation Catheter (K111295)
Intended use statement	The ComboCath OTW PTA Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The Coyote ES OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, infrapopliteal, popliteal, renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Design	Over-the-wire (OTW) Two lumen catheter shaft : (1) Lumen for balloon inflation and (1) Lumen for guidewire Thermoplastic polymer balloon Radiopaque marker	Over-the-wire (OTW) Two lumen catheter shaft : (1) Lumen for balloon inflation and (1) Lumen for guidewire Thermoplastic polymer balloon Radiopaque marker
Shaft and Balloon Material	Thermoplastic	Thermoplastic
Guidewire Compatibility	0.014" (0.36 mm)	0.014" (0.36 mm)
Compatible Sheath Size	5F	4F
Balloon Diameter	2.5, 3.0, 3.5, 4.0 mm	1.5, 2.0, 2.5, 3.0, 3.5, 4.0 mm
Balloon Length	40 mm	20, 30, 40 mm
Catheter Working Length	150 cm	90, 150 cm

Biocompatibility

The ComboCath™ OTW PTA Dilatation Catheter is constructed using commonly used materials in other medical devices. The ComboCath™ OTW PTA Dilatation Catheter passed all testing required to demonstrate biocompatibility per ISO 10993-1, Biological Evaluation of Medical Devices.

Summary:

Based on the intended use, product testing, and information provided in this notification, the subject device has been shown to function for its intended use and be substantially equivalent to the predicate device.