



February 21, 2017

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

Tryton Medical, Inc.
Elizabeth Lavelle
Regulatory Project Manager
1000 Park 40 Plaza, Suite 325
Durham, North Carolina 27713

Re: P150039

Trade/Device Name: TRYTON Side Branch Stent

Filed: October 30, 2015

Amended: January 19, 2016, February 22, 2016, and March 28, 2016

Product Code: MAF

Dear Ms. Lavelle:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the TRYTON Side Branch Stent. This device is indicated for improving the side branch luminal diameter of de novo native coronary artery bifurcation lesions (Medina Classification 1.1.1; 0.1.1; 1.0.1) with a side branch diameter stenosis of $\geq 50\%$ and a lesion length ≤ 5.0 mm, along with reference vessel diameters ≥ 2.5 mm to ≤ 3.5 mm in the side branch and ≥ 2.5 mm to ≤ 4.0 mm in the main branch. The device is intended for use in conjunction with commercially available balloon expandable drug-eluting coronary stents in the main branch. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at two years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, <http://www.fda.gov/udi>.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study every six (6) months during the first two (2) years of the study and annually thereafter, unless otherwise specified by FDA. The final report will be submitted to FDA within three (3) months of study completion. Two (2) copies of each report, identified as an "ODE Lead PMA Post-Approval Study Report" or "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

1. ODE Lead PMA Post-Approval Study – TRYTON Side Branch Stent PIVOTAL Randomized Controlled Trial (RCT): The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The TRYTON Side Branch Stent PIVOTAL Randomized Controlled Trial (RCT) is a prospective, multi-center, single blind controlled trial which enrolled 704 subjects randomized 1:1 to implantation of the TRYTON Side Branch Stent and a main branch approved drug-eluting stent (DES) (N=355) in the investigational device arm vs. side branch balloon angioplasty (POBA) and main branch implantation of an approved DES (N=349) in the control arm (Provisional cohort). The primary endpoint of the PIVOTAL RCT was clinically-indicated target vessel failure [TVF: defined as a composite of cardiac death, target vessel myocardial infarction (TV MI), and clinically-indicated target vessel revascularization (TVR)] of the TRYTON Side Branch Stent with main branch DES at 9 months.

You must collect and report to the Agency clinical outcomes through 3 years post-procedure on subjects enrolled in the PIVOTAL RCT. When appropriate or requested by FDA, you should submit PMA supplements requesting approval to update your Instructions for Use (IFU) to include follow-up data from this trial.

2. ODE Lead PMA Post-Approval Study – TRYTON Side Branch Stent Extended Access (EA) Confirmatory Study: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The TRYTON Side Branch Stent EA Confirmatory Study is a single-arm study, which enrolled 133 subjects treated with the TRYTON Side Branch Stent plus implantation of an approved DES in the main branch for treatment of native coronary artery bifurcation disease. The EA Confirmatory study mirrored the TRYTON Pivotal RCT study protocol enrollment criteria supplemented with an emphasis on proper side branch size selection, targeting patients with a side branch RVD ≥ 2.5 mm by visual estimate and ≥ 2.25 mm by QCA as assessed by the angiographic core laboratory. The primary endpoint of the EA Confirmatory Study was peri-procedural MI (PPMI) after percutaneous coronary intervention (PCI) defined as a CK-MB elevation >3 times the upper range limit within the first 48 hours after PCI.

You must collect and report to the Agency clinical outcomes through 1 year post-procedure on subjects enrolled in the EA Confirmatory Study. When appropriate or requested by FDA, you should submit PMA supplements requesting approval to update your Instructions for Use (IFU) to include follow-up data from this trial.

3. OSB Lead PMA Post-Approval Study – TRYTON Side Branch Stent New Enrollment Study: The Office of Surveillance and Biometrics (OSB) will have the lead for studies initiated after device approval. The TRYTON Side Branch Stent New Enrollment Study is a prospective, open label, multi-center evaluation of the PMA-approved, commercially-distributed TRYTON Side Branch Stent.

You must conduct a prospective, open label, multi-center evaluation of the TRYTON Side Branch Stent consisting of at least 300 US patients that receive the device post-approval. The effort should assess the rate of target vessel failure (TVF) within one year of index procedure, according to the clinical follow-up schedule in patients treated with the TRYTON Side Branch Stent according to its labeled indications for use. TVF is defined as the composite endpoint of cardiac death, myocardial infarction (Q Wave and Non-Q wave MI), and clinically-indicated target vessel revascularization. The evaluation should also assess the following endpoints: device success (i.e., attainment of $<30\%$ residual stenosis within the side branch using the TRYTON Stent without device malfunction), lesion success (attainment of $<30\%$ residual stenosis using any percutaneous method), and procedure success (lesion success without the occurrence of in-hospital MACE). Patients should be evaluated through 3 years post-procedure according to the clinical follow-up schedule.

You must provide an operator training program that includes an assessment plan to evaluate the effectiveness of training on the recommended procedure for TRYTON Side Branch Stent implantation. Within the post-approval effort as part of this training program, you must conduct an angiographic sub-analysis of at least 150 patients consecutively implanted by inexperienced operators to evaluate compliance with side branch reference vessel diameter criteria for TRYTON Side Branch Stent implantation. For this angiographic sub-analysis, you should provide quarterly interim progress reports to FDA.

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your OSB Lead PMA Post-Approval Study. Your PMA supplement should be clearly labeled as an "OSB Lead PMA Post-Approval Study Protocol" as noted above and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA. In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm>).

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process"

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm>).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or
2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at <http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm>.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
PMA Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Colin Tack at 240-402-6580 or Colin.Tack@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style. A large, light blue "FDA" watermark is visible in the background behind the signature.

for

Bram D. Zuckerman, M.D.
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health