DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

February 7, 2017

Lutonix, Inc.
Mr. John Carline
Director of Regulatory Affairs
9409 Science Center Dr.
New Hope, MN 55428

Re: P130024/S009
Trade/Device Name: Lutonix 035 Drug Coated Balloon PTA Catheter
Filed: July 8, 2016
Amended: November 9, 2016; December 13, 2016
Product Code: ONU

Dear Mr. Carline:

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) supplement for the Lutonix 035 Drug Coated Balloon PTA Catheter for expanding the indications to include in-stent restenosis and lesion lengths up to 300 mm. This device is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions up to 300 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm. We are pleased to inform you that the PMA supplement 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 36 months.

Continued approval of the 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 PMA 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 annually, unless otherwise specified by FDA. Two (2) copies of each report, identified as an "ODE 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 – *ISR and LL Cohorts of the Global SFA Registry Continued Follow-Up Study*: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The ISR and LL Cohorts of the Global SFA Registry Continued Follow-Up Study must be conducted per Protocol CL0004-01, Version 1.0, dated October 12, 2012. This study is a multi-center, single arm, prospective continued follow-up of the ISR and LL Cohorts of the Global SFA Registry. It will evaluate the long-term safety and effectiveness of the Lutonix Drug Coated Balloon in In-Stent Restenotic and Long Lesions. The safety and effectiveness endpoints to be assessed through 24 months post-procedure are: (1) the composite of freedom from all-cause peri-procedural (≤30 day) death and freedom at 1 year and 2 years from: index limb amputation, index limb re-intervention, and index limb death and (2) freedom from TLR at 1 year and 2 years, as defined in the protocol.

2. ODE Lead PMA Post-Approval Study – *SFA ISR IDE Continued Follow-Up Study*: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The SFA ISR IDE Continued Follow-Up Study must be conducted per Protocol CL0018-01, Version 4.0, dated July 6, 2016. This study is a multi-center, single arm, prospective continued follow-up of the SFA ISR Study (IDE G130244). It

will evaluate the long-term safety and effectiveness of the Lutonix Drug Coated Balloon in In-Stent Restenotic Lesions. The safety and effectiveness endpoints to be assessed through 24 months post-procedure are: (1) the composite of freedom from all-cause peri-procedural (≤30 day) death and freedom at 1 year and 2 years from index limb amputation (above or below the ankle), index limb re-intervention, and index-limb-related death and (2) primary patency at 1 year and 2 years, as defined in the protocol. Target Lesion Revascularization will also be reported at 3 years.

3. ODE Lead PMA Post-Approval Study – *Lutonix Long Lesion SFA Continued Follow-Up Study*: The Office of Device Evaluation (ODE) will have the lead for this clinical study, which was initiated prior to device approval. The Lutonix Long Lesion SFA Continued Follow-Up Study must be conducted per Protocol CL0017-01, Version 2.0, dated March 31, 2014. This study is a multi-center, single arm, prospective continued follow-up of the EU Long Lesion Trial. It will evaluate the long-term safety and effectiveness of the Lutonix Drug Coated Balloon in Long Lesions. The safety and effectiveness endpoints to be assessed through 24 months post-procedure are: (1) the composite of freedom from all-cause peri-procedural (≤30 day) death and freedom at 1 year and2 years from the following: index limb amputation and (above or below the ankle) and index limb re-intervention and (2) primary patency at 1 year and 2 years, as defined in the protocol. Target Lesion Revascularization will also be reported at 3 years.

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.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage http://www.fda.gov/devicepostapproval.

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 PMA 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
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10903 New Hampshire Avenue
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If you have any questions concerning this approval order, please contact Eleni Whatley at 301-796-6372 or Eleni.Whatley@fda.hhs.gov.

Sincerely,

Fernando Aguel -S

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