June 7, 2023

Endologix, LLC
Ms. Elizabeth Goldstein
Director, Regulatory Affairs
2 Musick
Irvine, California 92618

Re: P220021
Trade/Device Name: DETOUR™ System
Product Code: QWM
Filed: October 11, 2022
Amended: October 19, 2022; January 20, 2023; March 9, 2023

Dear Elizabeth Goldstein:

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 DETOUR System. The DETOUR System is indicated for use for percutaneous revascularization in patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis >70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The DETOUR System, or any of its components, is not for use in the coronary and cerebral vasculature. 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. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

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 one (1) year. 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 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. 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.

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.

You must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described below. Your PMA supplement should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted 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.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. DETOUR2 Continued Follow-up Study. This study should be conducted per protocol {STP 203 Rev F} (dated 16 March 2020). This study is a prospective, single-arm, multi-center follow-up of the pivotal DETOUR2 trial (G170083) that treated 220 patients at 36 investigational sites. It will evaluate the long-term safety and effectiveness of the DETOUR System. All 197 remaining subjects, active at the end of the 12-month evaluation, will continue to be followed at 24- and 36-months post-procedure.

   Follow-up at the timepoints will include the following assessments: arterial Duplex ultrasound examination to assess stent graft patency and stent-graft separation, venous Duplex ultrasound to assess for venous events (e.g., deep vein thrombosis), ABI, Rutherford Classification, Venous Clinical Severity Score and Villalta Scale, adverse events, all-cause mortality, target lesion revascularization, target vessel revascularization, major amputation.

2. PTAB1 Study: New-Enrollment Registry Study. The PTAB1 Study is a prospective, single arm, registry-based study designed to evaluate the real-world use of the DETOUR System in treated patients with symptomatic femoropopliteal lesions from 200 mm to 460 mm in length with chronic total occlusions (100 mm to 425 mm) or diffuse stenosis > 70% who may be considered suboptimal candidates for surgical or alternative endovascular treatments. The study will be implemented within the Society for Vascular Surgery Patient Safety Organization Vascular Quality Initiative registry sites in the United States (protocol received interactively on June 5, 2023). A maximum of 450 subjects will be enrolled with a target study population of at least 200 evaluable female and 200 evaluable male participants at the 12-month post-procedure follow-up visit.

Follow up visits/assessments will be completed at 1, 12, 24-, 36-, 48-, and 60-months post-procedure.

The primary effectiveness endpoint of freedom from clinically-driven target lesion revascularization (CD-TLR) as determined by an independent imaging Core Lab and the primary safety endpoint of freedom from a major adverse event (MAE) at 30 days post-procedure, defined as death, major amputation, and CD-TLR will be evaluated. Key secondary endpoints to be evaluated are:

- Perioperative and long-term:
  - Major amputation
  - All-cause mortality
  - Procedure-related Myocardial infarction
  - Deep Vein Thrombosis and/or Pulmonary Embolism
  - Incidental venous thrombosis or thrombus
  - Amputation-free survival
  - Major Adverse Limb Events (MALE)
  - Assisted patency
  - Secondary patency
- Perioperative only:
  - Procedure duration
  - Length of stay (from Index procedure to discharge)
  - Discharge status

In addition, vascular imaging (arterial and venous) sub-study of the first 55 females and 55 males enrolled will be completed. The sub-study will include Duplex imaging at 1-, 12-, 24-, and 36-months post-procedure to assess the endpoints of graft primary patency and venous thrombus within the vein containing the graft. Key endpoints to be evaluated are:

- Patency is defined as the absence of clinically driven target lesion revascularization (CD-TLR) and absence of recurrent target lesion diameter stenosis >50% by imaging (e.g., duplex ultrasound peak systolic velocity ratio peak systolic velocity ratio [PSVR] of >2.5 or as measured by invasive angiography) within the stent or immediately 1 cm above or below the treated segment.
- Venous thrombus within the vein containing the graft (i.e., thrombus or fibrin within the vein observed on imaging without symptoms)
- Symptomatic DVT
- Occlusive DVT
- Non-occlusive DVT

The study endpoint analyses will be summarized with descriptive statistics. The primary effectiveness endpoint will be analyzed by a Kaplan-Meier analysis, with censoring performed at the last informative time point. The primary safety endpoint will be presented in tabular fashion with the number of patients, patients with events, and patients evaluable at baseline (day 0). The percentage of patients with events will be provided.

PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

From the date of study protocol approval, you must meet the following timelines for PTAB1:

- First subject enrolled within 9 months
- 25% of subjects enrolled within 18 months
- 50% of subjects enrolled within 24 months
- 100% of subjects enrolled within 48 months

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

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 accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

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 Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (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. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

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" https://www.fda.gov/media/81431/download.

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 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, 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 https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

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 Home Page located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. 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 a copy 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, 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
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 Finn Donaldson at 301-796-9579 or Finn.Donaldson@fda.hhs.gov.

Sincerely,

Brian D. Pullin -S

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health