March 7, 2023

Bolton Medical, Inc. (dba Terumo Aortic)
Suzana Otano
Regulatory Affairs Manager
799 International Parkway
Sunrise, Florida 33325

Re: P200045/S002
Trade/Device Name: Relay®Pro Thoracic Stent-Graft System
Product Code: MIH
Filed: May 16, 2022
Amended: December 5, 2022

Dear Suzana Otano:

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 RelayPro Thoracic Stent-Graft System for the expansion of indications to include treatment of all lesions of the descending thoracic aorta (including transections and dissections), as well as for use as a distal extension for the Thoraflex™ Hybrid device (P210006).

The RelayPro Thoracic Stent-Graft System is indicated for the endovascular repair of all lesions of the descending thoracic aorta in patients having appropriate anatomy, including:

- Iliac or femoral access vessel morphology that is compatible with vascular access techniques, devices, and/or accessories;
- Non-aneurysmal aortic neck diameter in the range of:
  - 20 – 42 mm for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers and dissections
  - 19 – 42 mm for traumatic aortic injuries;
- Proximal landing zone (non-aneurysmal proximal aortic neck lengths for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers or non-dissected length of aorta proximal to the primary entry tear for dissections and length of aorta proximal to the tear for traumatic aortic injuries) of:
  - 15 mm for the 22 – 28 mm device diameters (***Bare Stent Configuration***)
  - 20 mm for the 30 – 38 mm device diameters (***Bare Stent Configuration***)
  - 25 mm for the 40 – 46 mm device diameters (***Bare Stent Configuration***)

  - 25 mm for the 22 – 38 mm device diameters (***Non-Bare Stent Configuration***)

  - 30 mm for the 40 – 46 mm device diameters (***Non-Bare Stent Configuration***)
- Non-aneurysmal distal aortic neck lengths for fusiform aneurysms and saccular aneurysms/penetrating atherosclerotic ulcers of:
  - 25 mm for the 24 – 38 mm device diameters
  - 30 mm for the 40 – 46 mm device diameters
- Non-aneurysmal distal landing zone of 20 mm for traumatic aortic injuries (22 mm – 46 mm device diameters) and dissections (24 mm – 46 mm device diameters)

The RelayPro Thoracic Stent-Graft System (NBS configuration) is indicated for the endovascular distal extension of the Thoraflex™ Hybrid device.

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. 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 2 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 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 have agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include, for your IDE and Post-Approval studies, respectively, a summary of the number of patients for

whom data are available, with the rates of major adverse events, all-cause mortality, lesion-related mortality, false lumen perfusion, retrograde extension, aortic expansion, fistula formation, stent graft kinking or twisting, secondary endovascular procedures, conversions to surgical repair, endoleaks, aortic rupture, compression, erosion, extrusion, stent-graft infection, stent-graft thrombosis, intra-graft thrombus formation, prosthesis migration, occlusions, stenoses, losses of device integrity, and other procedure or device-related events. Reasons for secondary interventions and conversion to open surgery as well as causes of lesion-related death and rupture are to be described. Additional relevant information from commercial experience within and outside the United States is also to be included. A summary of any explant analysis findings is to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

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 PMA supplements that include complete protocols of your post-approval studies described below. Your PMA supplements 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. *Continued Follow-up of the RelayPro Thoracic Stent Graft System Dissection Study Subjects:* This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available subjects from the IDE Dissection Study. A total of 56 subjects were enrolled in study and the remaining subjects will be followed for 5 years. Clinical outcomes will include all-cause mortality, lesion-related mortality, major adverse events, false lumen perfusion, retrograde extension, fistula formation, stent graft kinking or twisting, patency, device misalignment, stent fracture, secondary interventions, conversion to open repair, occlusions, stenosis, all types of endoleaks, stent graft migration (>10 mm), aortic expansion (>5 mm), aortic rupture, loss of device integrity, and other device-related events. These endpoints will be analyzed descriptively, and PAS reports submitted on a yearly basis.

2. *Continued Follow-up of the RelayPro Thoracic Stent Graft System Transection Study Subjects:* This is a prospective, single-arm, multi-center study that consists of continued follow-up of all available subjects from the IDE Transection Study. A total of 50 subjects were enrolled in study and the remaining subjects will be followed for 5 years, with a minimum of 25 subjects with evaluable 5 year data. Clinical outcomes will include all-cause mortality, lesion-related mortality, major adverse events, secondary interventions, conversion to open repair, occlusions, stenosis or kink, all types of endoleaks, stent graft migration (>10 mm), aortic dilatation (>5 mm), aortic rupture, compression, erosion, extrusion, stent-graft infection, stent-graft thrombosis, intra-graft thrombus formation, loss of device integrity, and other device-related events. These endpoints will be analyzed descriptively, and PAS reports submitted on a yearly basis.

3. *Registry Data Collection for Dissection:* You also agree to support and actively participate as a stakeholder in the Society for Vascular Surgery Patient Safety Organization governed Vascular Quality Initiative and/or establish a specific study arm for Dissection within the **T**erumo Aort**i**c

Global **E**ndovascular **R**egistry (TiGER) and undertake such activities to ensure that surveillance occurs for the Bolton RelayPro Thoracic Stent Graft System when used to repair Type B dissections in the descending thoracic aorta in 60 patients with acute dissections in 60 patients with chronic dissections. If collected via TiGER, a minimum of 50% of each indication will be from the US. This surveillance should monitor false lumen characteristics and freedom from dissection-related mortality, additional dissection-related intervention, dissection treatment success, the individual elements of the composite endpoint dissection treatment success, all-cause mortality, endovascular device penetration of the aortic wall, loss of device integrity, stent graft migration (>10 mm), device technical success at the time of the procedure, and device procedural success. The reports will include data at the following timepoints: preoperative, 30-day, 1-year, and yearly thereafter through 5 years. These endpoints will be analyzed descriptively, and PAS reports submitted every 6 months for the first 2 years and then annually thereafter.

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 above. 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 *the Registry Data Collection for Dissection:*

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the *Registry Data Collection for Dissection* as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6-month) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject’s last follow-up date

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, including complying with the PAS requirements outlined above, 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 Aurko Shaw at 301-796-3512 or Aurko.Shaw@fda.hhs.gov.

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander, Ph.D.
Acting Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health