



July 18, 2025

Boston Scientific Corp.
Sherry Kollmann
Senior Regulatory Affairs Manager
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: P130013/S074

Trade/Device Name: WATCHMAN FLX™ Left Atrial Appendage (LAA) Closure Technology,
WATCHMAN FLX™ Left Atrial Appendage Closure Device with Delivery
System,
WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device with
Delivery System

Dear Sherry Kollmann:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) completed its review of your premarket approval application (PMA) Supplement and issued an approval order on July 16, 2025. We inadvertently made an error and omitted “WATCHMAN FLX Pro” from the following sentence “Following catheter ablation for non-valvular atrial fibrillation (concomitantly or sequentially with WATCHMAN FLX™ implantation)...” in the indications for use listed in the approval letter. The corrected indications for use are as follows:

The WATCHMAN FLX™ Device and the WATCHMAN FLX™ Pro Device are indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Following catheter ablation for non-valvular atrial fibrillation (concomitantly or sequentially with WATCHMAN FLX™ or WATCHMAN FLX™ Pro implantation):

The WATCHMAN FLX™ Device and WATCHMAN FLX™ Pro Device are indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy.

We hope that this omission has not inconvenienced you. If you have any questions about this corrective action, please contact Katherine Trivedi at 240-402-6398 or Katherine.Trivedi@fda.hhs.gov.

Sincerely,

Rachel Neubrandner, PhD

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



July 16, 2025

Boston Scientific Corporation
Sherry Kollmann
Senior Regulatory Affairs Manager
One Scimed Place
Maple Grove, Minnesota 55311-1566

Re: P130013/S074

Trade/Device Name: WATCHMAN FLX™ Left Atrial Appendage (LAA) Closure Technology,
WATCHMAN FLX™ Left Atrial Appendage Closure Device with Delivery
System,
WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device with
Delivery System

Product Code: NGV

Filed: January 17, 2025

Amended: January 23, 2025

Dear Sherry Kollmann:

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 WATCHMAN FLX™ Left Atrial Appendage Closure Device with Delivery System, WATCHMAN FLX™ Left Atrial Appendage (LAA) Closure Technology, WATCHMAN FLX™ Left Atrial Appendage Closure Device with Delivery System, WATCHMAN FLX™ Pro Left Atrial Appendage Closure (LAAC) Device with Delivery System for expanding the indications to include patients following catheter ablation for non-valvular atrial fibrillation and to add a new post-implant drug regimen to the device labeling. This device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA₂DS₂-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Following catheter ablation for non-valvular atrial fibrillation (concomitantly or sequentially with WATCHMAN FLX implantation):

The WATCHMAN FLX Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA2DS2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy

Based upon the information submitted, the PMA supplement is approved. You may continue commercial distribution of the device upon receipt of this letter. 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 available 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 all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 3 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 must 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, under 21 CFR 814.82(a)(9), 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 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. **WATCHMAN FLX Pro OPTION PAS** – You have agreed to work with the American College of Cardiology (ACC) Left Atrial Appendage Occlusion (LAAO) Registry to ensure that FDA surveillance occurs for commercial use of the WATCHMAN FLX Pro Left Atrial Appendage Device with Delivery System. The OPTION Post Approval Analysis will be carried out to continue to characterize clinical outcomes associated with concomitant ablation and WATCHMAN implant in real world use.

Surveillance of real-world use will include a minimum of 3,000 consecutive subjects entered into the LAAO Registry. Of these subjects, at least 1,500 subjects will be subjects in whom a WATCHMAN FLX Pro device was successfully implanted during a concomitant ablation procedure. The remaining subjects will be subjects in whom a WATCHMAN FLX Pro device was successfully implanted following a historical ablation procedure that occurred between 3-12 months prior to the WATCHMAN FLX Pro implant. This surveillance should monitor the following registry collected data: procedure related events, including pericardial effusion, and device margin residual leak, device related thrombus, the rate of all-cause death, cardiovascular death, stroke (ischemic and/or hemorrhagic), major bleed, systemic embolism. Assessments should occur at hospital discharge, 45 days, 6 months, 1 year and 2 years. Event rates and patient baseline characteristics will be descriptively reported.

2. **WATCHMAN FLX Pro NOAC Alone PAS** – You have agreed to work with the American College of Cardiology (ACC) Left Atrial Appendage Occlusion (LAAO) Registry to ensure that FDA surveillance occurs for commercial use of the WATCHMAN FLX Pro Left Atrial Appendage Device with Delivery System. The NOAC Alone Post Approval Study will be carried out to continue to characterize clinical outcomes associated with the use of non-vitamin K oral anticoagulant (NOAC) alone as an alternative to an oral anticoagulant (OAC) and aspirin as the post-implant medication regimen for the WATCHMAN FLX Pro Left Atrial Appendage (LAA) Closure Device with Delivery System in a routine clinical setting. Surveillance of real-world use will include all consecutive subjects entered into the LAAO Registry who were successfully implanted with a WATCHMAN FLX Pro device, discharged, and prescribed NOAC alone, NOAC + aspirin, or dual antiplatelet therapy (DAPT) for 6 months from the date of the approval. This surveillance should monitor the following registry collected data: device- and procedure-related events, including pericardial effusion, and device margin residual leak, device related thrombus, device embolization, the rate of all-cause death, cardiovascular death, stroke (ischemic and/or hemorrhagic), major bleed, systemic embolism. Assessments should occur at hospital discharge, 45 days, 6 months, 1 year and 2 years. The above events will be descriptively compared between the cohorts of patients successfully implanted with a WATCHMAN FLX Pro device and discharged on NOAC Alone, NOAC + aspirin, and DAPT. The above event rates and baseline characteristics in the NOAC Alone, NOAC + aspirin, and DAPT cohorts will also be compared to the event rates in previously acquired LAAO Registry data prior to the NOAC Alone labeling implementation at hospital discharge, 45 days, 6 months, 1 year and 2 years. Patient

baseline characteristics and event rates will also be descriptively reported and compared to those of patients in the SURPASS (WATCHMAN FLX) post approval analysis.

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 OPTION PAS:

- 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 OPTION PAS and WATCHMAN FLX Pro NOAC Alone PAS 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 initiation, enrollment, and completion of the 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, available at 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. Under 21 CFR 814.39, 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 Part 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 available at <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. Additional information about changes that may require a PMA supplement are provided in 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>.

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production and process controls (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 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

<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 Part 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 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 Emily Olszewski at +1(301)796-2173 or Emily.Olszewski@fda.hhs.gov.

Sincerely,

Rachel Neubrandner, PhD
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