March 25, 2025

Bolt Medical, Inc.
Stephanie Onstot
Regulatory Affairs Manager
2131 Faraday Ave
Carlsbad, California 92008

Re: K250225
Trade/Device Name: Bolt Intravascular Lithotripsy (IVL) System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: January 24, 2025
Received: January 27, 2025

Dear Stephanie Onstot:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/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 (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

ARIEL G. ASH-SHAKOOR -S

Digitally signed by ARIEL G. ASH-SHAKOOR -S
Date: 2025.03.25 08:41:46 -04'00'

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250225

Device Name
Bolt Intravascular Lithotripsy (IVL) System

Indications for Use *(Describe)*
The Bolt Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, iliofemoral, popliteal, and infra-popliteal arteries. Not for use in the coronary, carotid, or cerebral vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Name, Address, Phone Number of Applicant

Bolt Medical, Inc.
2131 Faraday Ave
Carlsbad, CA 92008
Phone: 760-979-1890

Contact Person

Stephanie Onstot

Date Prepared

March 19, 2025

Device Name and Classification

Trade Name:	Bolt IVL™ Lithotripsy System
Common Name:	Catheter, angioplasty, peripheral, transluminal
CFR Classification:	21 CFR 870.1250
Classification Name:	Percutaneous catheter
Product Code:	PPN

Predicate Device

The primary predicate for the Bolt IVL Lithotripsy System is the Shockwave Medical Lithoplasty System (K161384) cleared by FDA on September 14, 2016.

Reference Device

The reference device for the Bolt IVL Lithotripsy System is the Shockwave Medical Intravascular Lithoplasty System (K203365) cleared by FDA on April 22, 2021.

Indications for Use / Intended Use

The Bolt Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, and infra-popliteal arteries. Not for use in the coronary, carotid, or cerebral vasculature.

Device Description

The Bolt Intravascular Lithotripsy (Bolt IVL) System is a proprietary balloon catheter and console designed to enhance percutaneous transluminal angioplasty by delivering calcium disrupting lithotripsy prior to balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive vascular deposit (stenosis) allowing low-pressure balloon dilatation of the stenosis.

The Bolt IVL catheter is delivered through the peripheral arterial system of the lower extremities to the lesion site. The balloon is partially inflated and the lithotripsy emitters generate pulsatile mechanical energy within the balloon at the target treatment site allowing subsequent dilatation of a peripheral artery stenosis using low balloon pressure. The Bolt IVL Catheter is a single-use device supplied sterile to the customer.

The Bolt IVL console delivers energy through the integrated catheter cabling to the emitters located inside the catheter balloon. The Bolt IVL Console is a non-sterile, reusable device.

Technological Comparison

The Bolt IVL System incorporates substantially equivalent design, dimensional, and performance specifications when compared to the predicate device. The Bolt IVL Catheter's fundamental scientific technology is the same as the predicate device: sheath and guidewire compatibility, usable catheter length, balloon diameters and lengths, as well as treatment and nominal pressure are consistent with the predicate device. The Bolt IVL System also has the same intended use, target population, and operating principles as the predicate device. The indications for use are nearly identical. Both systems use catheters that deliver acoustic energy to a blood vessel via a catheter which is connected via a cable to a console.

Summary of Performance Data

Objective evidence demonstrating the Bolt IVL System design output meets the product design input requirements as well as device performance characteristics conform to user needs and intended uses as defined in the product specification was provided. Testing was conducted in accordance with Bolt Medical's risk analysis and all applicable FDA guidance documents and relevant international standards. The following tests were conducted for the Bolt IVL Catheter:

- Catheter diameter and balloon profile
- Tensile strength
- Kink resistance / flexibility
- Catheter torsional strength
- Balloon Inflation / deflation time
- Minimum Burst Strength (RBP)
- Balloon compliance
- Fatigue (multiple inflations)
- Pushability and trackability
- Fluoroscopic visibility
- Particulate evaluation
- Pulsing cycles and output

The following tests were conducted for the Bolt IVL Console:

- Hardware design verification
- Electrical performance
- Electromagnetic compatibility
- Software verification and validation
- Life expectancy

Results demonstrate that the performance of the Bolt IVL System meets its design specifications and is safe and effective for its intended use.

Summary of Biocompatibility Testing

Biocompatibility testing was not required for the Bolt IVL Console as it is non-patient contacting. The Bolt IVL Catheter is categorized as "Externally communicating, Circulating Blood, (A) Limited exposure (<24hrs)". The biocompatibility of the device was assessed in accordance with ISO 10993-1:2020 – Biological evaluation of medical devices, Part 1 - Evaluation and tests within a risk management process

and in accordance with the provisions of 21 CFR 58 Good Laboratory Practices. The following testing was performed: cytotoxicity, sensitization, irritation/intracutaneous reactivity, system toxicity, and hemocompatibility. The biocompatibility test results confirm that the device is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic, nonhemolytic, and hemocompatible when evaluated under the respective test conditions.

Summary of Animal Testing

A chronic GLP study was conducted in a porcine in vivo model to determine the safety of delivering pulsatile mechanical energy to peripheral arteries with the Bolt IVL System. The histopathology evaluation revealed no trends between the treatment and control groups in injury, inflammation, fibrin, endothelialization or neointimal smooth muscle cells scores. The results demonstrated that the Bolt IVL System treatment is as safe as the control device in a chronic healthy porcine model.

Summary of Clinical Data

Restore ATK

To evaluate the safety and performance of the Bolt IVL System, Bolt Medical conducted a prospective, non-randomized, multicenter, single arm study (RESTORE ATK). Patients with peripheral arterial disease of Rutherford Category 2, 3, and 4 who were candidates for percutaneous therapy and met the trial criteria were consented and treated.

The target population for this analysis consisted of 95 adult subjects with calcific, stenotic, above the knee lesions in the peripheral vasculature enrolled at 10 sites in Croatia, Germany, and Austria. Baseline characteristics were consistent with a complex, calcified patient population. Severe calcification was assessed by an independent angiographic core laboratory in 93.7% of patients with an average lesion length of 96.0 mm. All 95 patients received treatment with the Bolt IVL System, and the procedures were completed with a low use of adjunctive therapies including pre- and post-dilatation balloons and only three post IVL stents.

The study met its primary safety endpoint. The lower bound of the 95% confidence interval for freedom from Major Adverse Events (MAE) at 30 days (96.8%) was above the performance goal (91.3%). Freedom from MAE ranged from 100% to 97.9%, with a lower 95% confidence interval of 96.9% to 93.5%. This interval was still within the performance goal of 91.3%.

The trial met its primary effectiveness endpoint. The lower bound of the 95% confidence interval for procedural success (96.9%) was above the performance goal (89.3%). Procedural success, defined as residual stenosis <50% with or without adjunctive therapy, was 100%.

Secondary effectiveness endpoints were also favorable. The secondary effectiveness endpoints include freedom from MAEs within 6 months. Freedom from MAE was 97.8% within 6 months. Procedural success is defined as residual stenosis <50% without adjunctive therapy and was achieved in 100% of patients. In addition, procedural success defined as residual stenosis ≤30% with or without adjunctive therapy was achieved in 86.3% of patients.

Target lesion patency by duplex ultrasound (DUS) was defined as freedom from ≥50% restenosis. Freedom from ≥50% restenosis at 30 days was 98.85% (95% CI: 96.64% to 100%). Freedom from ≥50% restenosis at 6 months was 66.32% (95% CI: 56.73% to 77.52%).

Functional outcomes including change in ankle-brachial index (ABI) and Rutherford Category showed improvement from baseline as compared to 30 days and six months in the majority of patients.

The RESTORE ATK trial was successful as both the primary effectiveness and primary safety endpoints were met. Secondary outcomes demonstrated similar positive findings. These results provide valid scientific evidence of the safety and effectiveness of the Bolt IVL System for lithotripsy-enhanced balloon dilatation of calcified, stenotic lesions in the peripheral vasculature.

Restore BTK

Bolt Medical, Inc. conducted a prospective, non-randomized, multicenter, single arm study, for the treatment of calcified, stenotic, below the knee lesions (RESTORE BTK) to assess the safety and performance of the Bolt IVL System. Adult patients with peripheral arterial disease of Rutherford Category 2-5 who were candidates for percutaneous therapy and met the trial criteria were consented and treated. Three (3) sites in Austria, Germany and Lithuania, enrolled subjects.

A total of 20 subjects and one (1) roll-in subject were consented and underwent the trial procedure (enrolled). All subjects completed a discharge and 30-day visit.

The clinical trial summary presents data and outcomes to 30 days. Baseline characteristics were consistent with a complex, calcified patient population. An independent angiographic core laboratory using the PARC scale assessed the severity of calcification to be severe in 83.3%. The average lesion length was 68.6 mm ± 39.6 mm with a corresponding percent diameter stenosis of 70.1%.

There was a 90% IVL device use rate (18/20), due to one console error preventing IVL treatment and one IVL catheter that could not cross the lesion. Eighteen (18) subjects received treatment with the Bolt IVL System, with low use of adjunctive therapies including pre- and post-dilatation balloons (22.2% and 16.7%, respectively). No stents were used in the procedures.

The primary safety endpoint of freedom from MAE was 100% (20/20) at 30 days. The lower bound of the 95% confidence interval for freedom from MAE at 30 days was 0.861 for the intention-to-treat (ITT) population.

The primary effectiveness endpoint was defined as the acute reduction in percent (%) diameter stenosis of the target lesion at the time of the Index Procedure. The 18 as-treated subjects (18/20) who successfully underwent the IVL procedure showed a mean acute reduction in percent diameter stenosis of 47.4% (95% CI: 32.6% to 62.1%).

There were no cardiovascular deaths, target limb major amputations, perforations, symptomatic thrombus or distal embolization events.

Freedom from Major Adverse Events (MAE)

	30 days (N=20)
Freedom from MAE	20/20 (100%)
Freedom from Death	20/20 (100%)
Freedom from clinically-driven revascularization of the target limb	20/20 (100%)
Freedom from unplanned major amputation of the target limb	20/20 (100%)

The study's secondary endpoint, procedural success, was defined as achieving a post-lithotripsy residual diameter stenosis of ≤50% (with or without adjunctive PTA therapy or

stenting), assessed via Core Lab quantitative angiography. In the as-treated analysis set, 100% (18/18) of subjects achieved procedural success, as evidenced by ≤50% residual stenosis.

The RESTORE BTK trial demonstrated successful intravascular lithotripsy-enhanced balloon dilatation of calcified, stenotic below the knee lesions in the peripheral vasculature with the Bolt IVL System.

Basis for Substantial Equivalence

The Bolt IVL System shares the same intended use and mechanism of action as well as similar technological characteristics as the predicate device. Any differences between the Bolt IVL System and the predicate device were evaluated through bench, animal, and clinical testing which demonstrated acceptable device performance and confirmed that there are no new questions of safety or effectiveness. Therefore, the Bolt IVL System is substantially equivalent to the predicate device.