August 24, 2026

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

Re: K260246
Trade/Device Name: SEISMIQ™ Intravascular Lithotripsy System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PPN
Dated: July 24, 2026
Received: July 24, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2026.08.24 14:26:55 -04'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260246

Please provide the device trade name(s).

SEISMIQ™ Intravascular Lithotripsy System

Please provide your Indications for Use below.

The SEISMIQ™ 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary – K260246

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

August 21, 2026

Device Name and Classification

Trade Name:	SEISMIQ™ Intravascular Lithotripsy System
Common Name:	Catheter, lithotripsy, peripheral, transluminal
CFR Classification:	21 CFR 870.1250
Classification Name:	Percutaneous catheter
Product Code:	PPN

Predicate Device

The primary predicate for the SEISMIQ Intravascular Lithotripsy (IVL) System is the SEISMIQ Intravascular Lithotripsy System (Previously named the Bolt IVL System, K250225) cleared by FDA on March 25, 2025.

Reference Device

The reference device for the Bolt IVL Lithotripsy System is the Shockwave Medical Lithoplasty System S^4 (K191840) cleared by FDA on August 7, 2019.

Indications for Use / Intended Use

The SEISMIQ (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.

Device Description

The SEISMIQ Intravascular Lithotripsy 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 and facilitates the passage of blood.

The SEISMIQ 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 SEISMIQ IVL Catheter is a single-use device supplied sterile to the customer.

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

Technological Comparison

This 510(k) Premarket Notification is being submitted for minor modifications to the SEISMIQ™ IVL System. The product line extension adds additional catheter sizes with a smaller ballon diameter and length to the SEISMIQ IVL System portfolio.

To increase the size range of the system, the additional catheter sizes include a smaller ballon diameter and length as compared to catheters cleared under K250225. Differences between the two catheters do not raise new questions of safety and effectiveness.

The SEISMIQ IVL System has the same intended use principles of operation and has substantially equivalent technological characteristics, including the same fundamental scientific technology, design, energy source, shelf life and sterilization as the predicate IVL System.

Summary of Performance Data

Objective evidence demonstrating that the SEISMIQ IVL System design output meets the product design input requirements as well as that 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 procedures, and all applicable FDA guidance documents and relevant international standards. Testing included:

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

Results demonstrate that the performance of the SEISMIQ IVL System meets its design specifications and demonstrates substantial equivalence for its intended use.

Summary of Biocompatibility Testing

Biocompatibility testing was conducted on the predicate device (K250225) in accordance with ISO 10993-1:2020 and FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and leveraged for the subject device.

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, and submitted as part of K250225. There have been no modifications made to the subject device that impact the delivered therapy of the SEISMIQ IVL System. Therefore, data from K250225 is leveraged for the subject device submission.

Summary of Clinical Data

Clinical evidence which evaluated the safety and performance of the Bolt IVL System was submitted as part of K250225 for above the knee (RESTORE ATK) and below the knee (RESTORE BTK), and is leveraged for the subject device submission. There have been no modifications made to the subject device that impact the delivered therapy of the SEISMIQ IVL System.

Basis for Substantial Equivalence

The SEISMIQ 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 SEISMIQ IVL System and the predicate device were evaluated through bench testing which demonstrated acceptable device performance and confirmed that there are no new questions of safety or effectiveness. Therefore, the SEISMIQ IVL System is substantially equivalent to the predicate device.