DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 06, 2016

Forge Medical, Inc.
c/o Mason Diamond, DDS
Texel Fortis, LLC
150 Levinberg Lane
Wayne, NJ 07470

Re: K153259
Trade/Device Name: VasoStat™ Hemostasis Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: November 7, 2015
Received: November 10, 2015

Dear Dr. Diamond:

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153259

Device Name
VasoStat™ Hemostasis Device

Indications for Use *(Describe)*
The VasoStat™ Hemostasis Device is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or lower leg, including radial artery catheterization, pedal or tibial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter Name:	Forge Medical, Inc
Submitter Address:	791 West Broad Street, Suite 102 Bethlehem, PA 18018
Phone Number: Fax Number:	215-605-3225 866-244-8988
Contact Person:	Mason Diamond, DDS Texel Fortis, LLC 150 Levinberg Lane Wayne, NJ 07470 Phone: 508-333-0108 Fax: 973-305-0213
Date Prepared:	10 December, 2015
Device Trade Name:	VasoStat™ Hemostasis Device
Common Name	Vascular compression device
Classification Name Number and Product Code:	Vascular clamp 870.4450 DXC
Predicate Devices:	VasoStat™ Hemostasis Device (Forge Medical): K123041 RadAR™ Vascular Compression Assist Devices (Advanced Vascular Dynamics): K142122
Device Description	VasoStat™ Hemostasis Device is a device that is adhered to the patient's skin directly over a percutaneous vascular puncture site and allows the application of adjustable compression to the puncture site to achieve hemostasis. The device is composed of a flexible thermoplastic base that has the ability to conform to the patient's anatomy (e.g. lower arm, upper arm, foot) and is secured to the skin with biocompatible adhesive pads. A plunger component passes through the base, applies targeted pressure to the puncture site through a ratcheting mechanism, and can be adjusted with one hand to apply the appropriate pressure necessary to promote hemostasis. VasoStat has the ability to vary the amount of pressure applied to the puncture site to promote hemostasis while minimizing the risk of thrombosis. The device

	design and materials ensure that the product is comfortable for the patient to wear while their puncture site stops bleeding. Once hemostasis is achieved (in approximately 15 to 45 minutes), the device is easily removed and discarded.
Statement of Indications for Use	The VasoStat™ Hemostasis Device is indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or lower leg, including radial artery catheterization, pedal or tibial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.
Summary of Technological Characteristics	The VasoStat™ Hemostasis Device is designed to provide local compression to the puncture site into a blood vessel of the arm or lower leg, including arterial sheath placement and dialysis shunt access. The degree of pressure is designed to stop bleeding without causing vessel thrombosis. The VasoStat™ Hemostasis Device is the same as that previously cleared by the FDA (K123041), and functions in the same way. Though different in design, the VasoStat™ Hemostasis Device provides sufficient compression to stop bleeding in pedal arterial catheterizations similar to the RadAR™ Vascular Compression Assist Devices, which also utilize compression to stop bleeding (K142122).
Performance Testing	Since this submission applies to the VasoStat™ Hemostasis Device to revise the indications for use without any changes to device design, the benchtop and animal testing reported in K123041 has been leveraged to demonstrate that the submitted device is appropriate for the new indications for use. Similarly, biocompatibility for this device has already been established per ISO-10993 (K123041). Furthermore, the VasoStat™ Hemostasis Device was retrospectively evaluated in three-hundred fourteen (314) patients following transpedal access for peripheral vascular disease intervention. The analysis concluded that the VasoStat™ Hemostasis Device was capable of achieving hemostasis following transpedal catheterization with low rates of pseudo-aneurysm and access site occlusion.
Substantial Equivalence	The VasoStat™ Hemostasis Device is Substantially Equivalent to predicate VasoStat™ Hemostasis Device (K123041), with respect to technical and design features. The Indications for Use and Mode of Action is Substantively Equivalent to the RadAR™ Vascular Compression Assist Devices (K142122).
Conclusion	The information discussed above demonstrates that the VasoStat™ Hemostasis Device is substantially equivalent to the predicate device.

Summary of Substantial Equivalence

Feature	VasoStat™ Hemostasis Device	VasoStat™ Hemostasis Device	RadAR™ Vascular Compression Assist Devices
510(k) Number	K153259	K123041	K142122
Class	II	II	II
Classification	Vascular clamp	Vascular clamp	Vascular clamp
Regulation	870.4450	870.4450	870.4450
Product Code(s)	DXC	DXC	DXC
Indications for Use	…indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or lower leg, including radial artery catheterization, pedal or tibial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.	…indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm, including radial artery catheterization, arterial or venous line removal, hemodialysis, and in patients on anticoagulation therapy.	…indicated for use by medical professionals to promote hemostasis following a catheterization or other puncture into a blood vessel in a patient's arm or leg, including radial brachial, dorsalis, pedis, or tibial blood vessels, arterial or venous line or sheath removal, hemodialysis, and in patients on anticoagulation therapy.
Mode of Action	Compression	Compression	Compression
Composition	Same a predicate	Molded Polypropylene/Polyethylene Foam/Acrylic Adhesive	Not available
Biocompatibility	Established biocompatible materials	ISO 10993 – Part 5 ISO 10993 – Part 10	Established biocompatible materials