March 31, 2020

EnsiteVascular, LLC
℅ Shree Koushik
Senior Regulatory Consultant
Tamm Net, Inc.
3238 Turtle Lake Drive SE
Marietta, GA 30067

Re: K192413
Trade/Device Name: SiteSeal™ Femoral Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: February 20, 2020
Received: February 24, 2020

Dear Shree Koushik,

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Rachel Neubrander
Assistant 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192413

Device Name
SiteSeal™ Femoral Compression Device

Indications for Use *(Describe)*

The SiteSeal™ Femoral Compression Device is indicated for use in the compression of the femoral artery or vein after vessel cannulation.

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.

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9.1 Sponsor

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9.2 510k Submission Correspondent:

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9.3 Date Prepared:

March 31, 2020

9.4 Device Information

Proprietary Name:	**SiteSeal™ Femoral Compression Device**
Common Name:	Adjunctive Compression Device
Device Category:	Class II
Product Code:	DXC Regulation
Number:	870.4450
Classification Name:	Vascular Clamp

9.5 Predicate Device

K080206 – FemoStop® Femoral Compression System.

9.6 Device Description

Components-

The Site Seal System consists of a Coated Vicryl™ Suture, a hemostatic powder, a spring-loaded polypropylene SiteSeal™ device, tincture of benzoin and four adhesive

dressings in a non-sterile kit. Each component in the kit is individually packaged in the original sterile package. The suture is used to approximate soft tissue on either side of and just above a femoral vessel. The hemostatic powder is poured onto the access site and suture entry/exit sites to control minor external bleeding and exudate from sutures and/or endovascular procedures. The free ends of the suture (after approximating the soft tissue on either side and above the CFA with a first half-knot) are tied tightly around the polypropylene SiteSeal™ device with a second full knot to anchor the device to the skin and provide counter pressure. The internal coil springs apply invariant mechanical pressure against the 3-dimensional, asymmetric SiteSeal™ skin contact surface to induce hemostasis. The asymmetric contact surface is designed so that the physical pressure is greatest towards the heart. A polypropylene roof is placed. Tincture of benzoin and three adhesive dressings stabilize and secure the device to the skin.

Prior to the patient being ambulated, the transparent adhesive dressing, device, loose powder, and suture are removed.

Mechanism of action –
A suture is placed in the soft tissue on both sides and above the access site. The "Z-stitch" anchors the SiteSeal to the skin surface creating an inverted skin "channel" aligned with the vessel.

Hemostatic powder covers the access site and suture penetrations to absorb exudate and control minor external bleeding.

The SiteSeal™ device has a three-dimensional skin contact surface that is aligned with the inverted skin channel. The device is pressed tightly against the access site while the sheath is removed.

After sheath removal the SiteSeal™ device is anchored to the access site by tying the device to the skin using the loose ends of the suture. Compressed internal springs apply pressure to the skin external to the vessel such that higher pressure is towards the heart. A polypropylene roof is placed securely over the device. Adhesive strips adhere to the roof and stabilize the SiteSeal™ device.

The springs help modulate heartbeat pressure variation without stopping blood flow through the vessel. The pressure allows continuous blood flow past the access site for a time sufficient to achieve hemostasis.
Hemostasis occurs during the time that the SiteSeal™ device is deployed.

The adhesive strip is removed, the sutures are cut and removed, the device is

disposed of, any excess powder is brushed off. The patient ambulates immediately.

Nothing is left in the body.

9.7 Intended Use

The SiteSeal™ Femoral Compression Device is indicated for use in the compression of the femoral artery or vein after vessel cannulation.

9.8 Substantial Equivalence

SiteSeal™ has substantially equivalent indications to the FemoStop® Femoral Compression System (K080206) predicate in that they are both indicated for use in the compression of the femoral artery or vein after vessel cannulation.

Both devices provide a focused invariant pressure to the access site. Both devices provide deep hemostasis at the arteriotomy and topical hemostasis at the skin incision site. Finally, although both devices are constructed from inert polymeric materials, the SiteSeal™ is designed to contact the smallest skin area necessary to achieve hemostasis and includes a hemostatic powder to facilitate blood clotting at the surface of the incision site. The difference in device surface contact area and the inclusion of a hemostatic powder is not considered to detract from a substantial equivalence claim.

The subject device and the predicate device are made from materials that have demonstrated satisfactory biocompatibility and are sterile, single use devices.

SiteSeal™ device achieves hemostasis by compressing the femoral vessel catheter insertion site, i.e., it has a similar intended use compared to the predicate device. Bench testing demonstrated that SiteSeal™ is similar to FemoStop® System in that both use external pressure to control blood flow through a vessel for a time sufficient to achieve hemostasis.

The IDE clinical study summarized below in the Clinical Study Section demonstrated that the Z-stitch blind suturing used with the SiteSeal™ device was safe and did not raise new questions of safety and effectiveness.

Based on bench and clinical testing, on the similarities in the intended and indications for use and the mitigation of the risk of differences in technology characteristics as described above and clinical testing EnsiteVascular™ concludes that SiteSeal™ is substantially equivalent to FemoStop®.

9.9 Performance Testing

Biocompatibility Testing – Biocompatibility testing (cytotoxicity, irritation and sensitization) was completed.

In vitro Testing – Bench testing versus FemoStop® Femoral Compression System demonstrated that both systems allow the same amount of simulated blood flow through a vessel at recommended pressures.

Bench testing showed that the compression of the 316SS springs is reproducible and consistent.

Bench testing showed that the suture bursting strength exceeds that of both springs' maximum force.

Pressure analysis of SiteSeal™ and the predicate showed that both systems provide predictably similar pressure to the site.

Endotoxin LAL Test was completed successfully.

Clinical Study – EnsiteVascular conducted a pivotal IDE clinical study to evaluate whether the SiteSeal™ device is safe to use as intended.

Pivotal IDE Clinical Study Summary

The pivotal IDE clinical study was conducted to evaluate the safety of the blind Z-stich procedure used to keep the SiteSeal™ device in place. The IDE clinical study was a prospective, single-arm, nonrandomized study conducted at 2 medical centers, both of which were in the United States. The study involved patients undergoing percutaneous cardiac or peripheral vascular interventional catheterization procedures. There were 2 roll-in SiteSeal device patients, who provided training and ensured investigator familiarity with the device, and 89 pivotal ("main analysis") SiteSeal device patients. Originally the study was to enroll 90 patients, but the study enrolled only 89 patients. Two (2) pivotal patients each had 2 access sites evaluated, in the right and left femoral arteries, such that 91 access sites were evaluated in the 89 pivotal patients.

At the catheterization laboratory site, patients were screened through a standard of care medical history. After determining that the patient qualified for enrollment into the study, the investigator or delegated study personnel obtained an informed consent. There were inclusion and exclusion criteria, which included pre-procedure inclusion and exclusion criteria and intra-procedural exclusion criteria. If, after catheterization but prior to femoral artery closure, a patient remained eligible for the study, the Site-Seal device was deployed at the femoral artery access site. Follow-up for the study patients was at a visit 30 days ± 7 days after the catheterization procedure. An ultrasound sub-study was done, which involved 58 pre-procedure ultrasounds representing 2 ultrasounds in the 2 roll-in patients and 56 ultrasounds in 54 pivotal patients (with 2 pivotal patients each having 2 access sites) done at one of the study sites, and 57 post-procedure ultrasounds representing 2 ultrasounds in the 2 roll-in patients and 55 ultrasounds in 53 pivotal patients (with 2 pivotal patients each having 2 access sites) done at the office practice of one of the 2 principal investigators in the study. All post-procedure ultrasounds were done after discharge following the catheterization procedure, at an average of 19.5 ± 7.3 days after the catheterization procedure, with a range of 3 – 33 days post-procedure.

The primary safety endpoints were 1) common femoral artery laceration (or needle puncture) and 2) common femoral nerve puncture causing an incident of involuntary leg muscle contraction with auditory response, resulting from blind placement of the Z-stitch in the soft tissue above the femoral bundle.

The secondary safety endpoints were 1) patient discomfort evaluated at a) discharge from the catheterization lab and b) 24 hours post-procedure (per 24-hour phone interview), using a scale of 0-10 with 10 being intense pain, and 2) the 30-day incidence of major complications and the 30-day incidence of minor complications (per patient follow-up visit).

The baseline demographics and characteristics for the patients in the SiteSeal device IDE clinical study are summarized in the following two tables.

Baseline Demographics of Patients in SiteSeal Device IDE Clinical Study

Demographic		Interventional (N = 89 Patients)
Age	Mean ± SD	69.9 ± 9.12 years
	Range	45 – 90 years
	Number	89
Sex		Men: 67.4% (60/89)
		Women: 32.6% (29/89)

Baseline Characteristics of Patients in SiteSeal Device IDE Clinical Study

Characteristic		Interventional (N = 89 Patients)
Height (ft)	Mean ± SD	5.6 ± 0.39
	Range	4.1 – 6.4
	Number	89
Weight (lbs)	Mean ± SD	193 ± 43.9
	Range	84 – 320
	Number	89
Body Mass Index (kg/m^2)	Mean ± SD	29.5 ± 5.84
	Range	15.4 – 44.4
	Number	89
Systolic Blood Pressure (mm Hg)	Mean ± SD	135.0 ± 18.0
	Range	100 – 175
	Number	89
Diastolic Blood Pressure (mm Hg)	Mean ± SD	71.0 ± 10.3
	Range	50 – 97
	Number	89
History of Peripheral Artery Disease [1]	Yes	63.2% (55/87)
	No	36.8% (32/87)
Femoral Artery Site	Right	74.7% (68/91)
	Left	25.3% (23/91)
Introducer Sheath Size Used (Fr)	Mean ± SD	7.3 ± 2.9
	Range	4 – 14
	Number	91
Previous Arterial Puncture in > 30 Days [2]	Yes	31.8% (28/88)
	No	68.2% (60/88)
Type of Catheterization	Cardiac	39.3% (35/89)
	Peripheral Vascular	60.7% (54/89)
Procedure Time [3] (min)	Mean ± SD	74.2 ± 32.1
	Range	30 – 80
	Number	89

[1] Two (2) patients had missing data.

[2] One (1) patient had missing data.

[3] The procedure time begins when the common femoral artery is accessed under ultrasound guidance, and ends when all devices have been removed from the common femoral artery. The procedure time does not include recovery time for hemostasis to occur.

Study Results:

Primary Safety Endpoints

No cases of common femoral artery laceration or common femoral nerve puncture were observed in the study. The ultrasound sub-study, the results of which are

discussed below, showed no common femoral artery laceration and no common femoral vein laceration. It was concluded that the risk of either common femoral artery laceration or common femoral nerve puncture is less than 3.3% with 95% confidence (one-sided 95% upper confidence limit).

Major Complications Secondary Safety Endpoint

The following table shows the incidence of major complications in the interventional patients in the SiteSeal device IDE clinical study.

Incidence of Major Complications in Patients in SiteSeal Device IDE Clinical Study

Description of Event	Interventional (N = 91 Access Sites)
Vascular repair, or the need for vascular repair, (via surgery, ultrasound guided compression, transcatheter embolization, or stent graft)	0% (0/91)
Access site-related bleeding requiring transfusion 1	1.1% (1/91)
Any new ipsilateral lower extremity ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram	0% (0/91)
Surgery, or the need for surgery, for access site-related nerve injury	0% (0/91)
Permanent (lasting > 30 days) access site-related nerve injury	0% (0/91)
Access site-related infection requiring intravenous antibiotics and/or extended hospitalization	0% (0/91)
Total Major Access Site-Related Complications	1.1% (1/91)

[1] This access-site related bleeding requiring transfusion occurred in a patient with previously undiagnosed Factor 8 deficiency.

Minor Complications Secondary Safety Endpoint

The following table shows the incidence of minor complications in the interventional patients in the SiteSeal device IDE clinical study.

Incidence of Minor Complications in Patients in SiteSeal Device IDE Clinical Study

Description of Event	Interventional (N = 91 Access Sites)
Non-treated pseudoaneurysm documented by ultrasound	0% (0/91)

Non-treated arteriovenous fistula documented by ultrasound 1	1.1% (1/91)
Pseudoaneurysm treated with ultrasound guided thrombin injection, or ultrasound-guided fibrin adhesive injection	0% (0/91)
Access site hematoma ≥ 6 cm 1	1.1% (1/91)
Access site-related bleeding requiring > 30 minutes to achieve hemostasis 2	7.7% (7/91)
Late (following hospital discharge) access site-related bleeding 3	2.2% (2/91)
Ipsilateral lower extremity arterial emboli	0% (0/91)
Transient loss of ipsilateral lower extremity pulse	0% (0/91)
Ipsilateral deep vein thrombosis 1	1.1% (1/91)
Access site-related vessel laceration	0% (0/91)
Transient access site related nerve injury	0% (0/91)
Access site wound dehiscence	0% (0/91)
Localized access site infection treated with intramuscular or oral antibiotics	0% (0/91)
Total Minor Access Site-Related Complications 4	13.2% (12/91)

[1] The complications of AV fistula, hematoma ≥ 6 cm, and ipsilateral DVT occurred in the same patient.

[2] In all 7 patients with access site-related bleeding requiring > 30 minutes to achieve hemostasis, activated clotting time (ACT) was not obtained prior to SiteSeal device removal, such that the anticoagulation status of each patient prior to SiteSeal device removal was not known.

[3] One of the 2 patients with late access site-related bleeding had previously undiagnosed Factor 8 deficiency. The second patient with late-access site bleeding also had bleeding requiring > 30 minutes to achieve hemostasis.

[4] The 12 minor complication events occurred in 9 patients.

Ultrasound Sub-Study Results

The only abnormalities detected in the ultrasound sub-study were 2 hematomas < 6 cm in size in the post-procedure ultrasounds in 2 pivotal patients, which were not detected in the pre-procedure ultrasounds in these patients. One of these hematomas occurred in a patient who had previously undiagnosed Factor 8 deficiency.

Patient Discomfort Secondary Endpoint

The mean discomfort score, using a scale of 0 – 10, was 0.45 ± 1.63 with a 95% two-sided confidence interval of 0.11 – 0.79 at discharge, and was 1.02 ± 2.17 with a 95% two-sided confidence interval of 0.56 – 1.48 after 24 hours.

Eighty-two (82) cases (90.1%, 82/91) experienced no discomfort at discharge and 67

cases (76.1%, 67/88) experienced no discomfort after 24 hours. Three (3) patients did not have a discomfort score after 24 hours.

At discharge, 2 patients experienced a discomfort score of 6 or higher. After 24 hours, 5 patients experienced a discomfort score of 6 or higher.

IDE Clinical Study Conclusion
The results of the SiteSeal device pivotal IDE clinical study demonstrate that the SiteSeal device is safe to use as intended as an adjunctive femoral compression device.

9.10 Conclusion

EnsiteVascular™ believes that, as a result of the in vitro testing, clinical testing and supporting biocompatibility, SiteSeal™ is as safe and effective for use in the compression of the common femoral artery or vein after vessel cannulation as the predicate device and therefore is substantially equivalent to the predicate device, FemoStop® Femoral Compression System (K080206).