July 29, 2022

Koag LLC
David Lang
Chief Executive Officer
790 Rarity Bay Pkwy
Vonore, Tennessee 37885

Re: K220566
Trade/Device Name: Vascette VCD
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 1, 2022
Received: April 4, 2022

Dear David Lang:

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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220566

Device Name
Vascette HP

Indications for Use *(Describe)*
Vascette HP is intended for use as a temporary topical dressing for the management of bleeding from vascular access sites and percutaneous catheters.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6. 510(k) SUMMARY (AS REQUIRED BY 21 CFR §807.92(c))

510(k) Owner Information:

KOAG International, LLC
790 Rarity Bay Parkway
Vonore, TN 37885
Contact person: David Lang
Phone: 470-755-9291
Email: dlang@koag.life
Date of Preparation: February 25, 2022

Device Information:

Proprietary name:	Vascette® HP, Topical Hemostatic Pad
Regulation Class.:	Unclassified
Classification name:	Dressing, Wound, Drug
Product Code:	FRO

Predicate Device: SoftSeal®-STF (K090100)

Description of the Device:

Vascette HP is a 2 inch x 2 inch (50mm x 50mm) square, single use, multi-layer temporary topical wound dressing applied over vascular puncture sites and percutaneous catheter sites. There are two tissue contacting components in the device: 1) the polyethylene adhesive foam border and 2) the plant derived modified starch (carboxyl starch sodium (CMS)) hemostatic foam. The hemostatic foam is hydrophilic and dehydrates blood at the wound site, producing hemostasis. The device is non-invasive, and removal protocol is the same as other temporary topical hemostatic pads. Sterilization of the device is performed utilizing gamma irradiation to SAL 10^{-6}.

Intended Use:

Vascette HP is intended for use as a temporary topical dressing for the management of bleeding from vascular access sites and percutaneous catheters. The device is to be used under the care of a health care professional.

Summary of Technical Characteristics Compare to the Predicate Device:

Comparison of the technological characteristics of the subject device, Vascette HP, and predicate device, SoftSeal®-STF, show that the two devices are similar in dimensional design, pH, and intended use as topical hemostatic pads. Both devices have similar packaging and gamma irradiation sterilization methodology.

The primary difference between the subject and predicate devices is the composition of hemostatic agents. Vascette HP contains plant-based polysaccharide foam hemostatic material while SoftSeal-STF contains animal-based, non-woven chitosan fibers.

Nonclinical Test Submitted: Animal Study

A porcine model was utilized in both the GLP and non-GLP studies. Veterinary assessments inclusive of physical examination, body condition score, body weight, clinical monitoring and clinical pathology suggested that the animal was clinically healthy at study enrollment. A pre-clinical animal GLP evaluation was conducted according to applicable regulations, 21 CFR Part 58, Good Laboratory Practices Regulations, to assess the achievement of hemostasis in percutaneous arterial access sites.

The subject device, Vascette HP, achieved hemostasis within five (5) minutes and forty-five (45) seconds in all test animals. In addition, there were no clinically significant findings on gross pathology that were deemed related to the subject device.

Nonclinical Test Submitted: Performance Testing

Bench performance testing of the Vascette HP consisted of visual inspection, dimensional measurements, liner peel testing and material certifications. Test results confirmed Vascette HP is substantially equivalent to the predicate device with respect to safety and effectiveness.

Additional Nonclinical Performance Testing that was conducted consists of the following:

Biocompatibility Test	**Standard Followed**	**Outcome**
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Maximum Sensitization	ISO 10993-10	Non-toxic
Intracutaneous Reactivity	ISO 10993-10	Non-toxic
Acute Systemic Toxicity	ISO 10993-11	Non-toxic
Pyrogenicity	ISO 10993-11	Non-pyrogenic

Sterilization and Packaging	**Standard Followed**	**Outcome**
Sterilization Validation	ISO 11137-2	SAL 10^{-6} achieved
Bubble Leak Testing	ASTM F2096-11	Pass
Seal Strength Test	ASTM F88	Pass
Distribution Simulation	ASTM 4196-16	Pass
Six Month Accelerated Aging	ASTM 1980-16	Pass
Two Year Accelerated Aging	ASTM 1980-16	Pass

Clinical Tests Submitted:

Evaluation in a clinical setting has not been performed.

Conclusions:

The Vascette HP is substantially equivalent to the predicate device with respect to intended use, Indications for Use, design, sterilization, and biocompatibility. The non-clinical testing data provided support the substantial equivalence of the device to the predicate device. Therefore, any minor differences between the subject device and the predicate do not raise any different safety or effectiveness issues with the subject device.