May 29, 2025

Reflow Medical, Inc.
Lori Grace
Sr. Director, Regulatory Affairs
208 Avenida Fabricante, Suite 100
San Clemente, California 92672

Re: DEN240048
Trade/Device Name: Spur Peripheral Retrievable Stent System
Regulation Number: 21 CFR 21 CFR 870.5110
Regulation Name: Peripheral temporary and retrievable stent system
Regulatory Class: Class II
Product Code: SEU
Dated: September 19, 2024
Received: September 20, 2024

Dear Lori Grace:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Spur Peripheral Retrievable Stent System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Spur® Peripheral Retrievable Stent System is intended as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Spur Peripheral Retrievable Stent System, and substantially equivalent devices of this generic type, into Class II under the generic name peripheral temporary and retrievable stent system.

FDA identifies this generic type of device as:

> **Peripheral temporary and retrievable stent system**. A peripheral temporary and retrievable stent system is a temporary scaffold placed into the peripheral vasculature via a delivery catheter system for treating stenotic lesions. The device is designed to be retrieved and removed following successful treatment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 20, 2024, FDA received your De Novo requesting classification of the Spur Peripheral Retrievable Stent System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Spur Peripheral Retrievable Stent System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Spur Peripheral Retrievable Stent System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Risks to Health	**Mitigation Measures**
Infection	Sterilization validation Shelf life testing Pyrogenicity testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing
Device misuse, damage, and/or malfunction, resulting in intra-procedural complications, including: • Vascular injury (e.g. perforation, dissection, aneurysm, fistula) • Embolic events • Vessel spasm • Hemodynamic instability • Prolonged procedure time	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Post-procedural events (short- or long-term), including: • Additional intervention/surgery • Thromboembolic episodes • Restenosis	Clinical performance testing Animal performance testing Biocompatibility evaluation Labeling

In combination with the general controls of the FD&C Act, the Peripheral temporary and retrievable stent system is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
   (i) Analysis of all adverse events, including serious and non-serious complications; and
   (ii) Clinically meaningful endpoints that assess device performance and clinical benefit.

(2) Animal performance testing must evaluate the device's performance in a physiological environment, including assessing vascular compatibility, deployment and retrieval behavior, and acute and subacute adverse effects (e.g. dissection, perforation, spasm, hemorrhage, thrombosis, stenosis). Evaluations must include:
   (i) Post-procedural examination of the catheter for thrombus or damage;
   (ii) In-life clinical observations of the test animals;
   (iii) Clinical pathology assessment;
   (iv) Imaging to assess vascular response and patency;
   (v) Complete gross necropsy;
   (vi) Examination of downstream tissue beds for particulate or thromboembolic events; and
   (vii) Comprehensive target tissue histopathology and histomorphometry evaluation.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following characteristics must be evaluated:
   (i) Dimensional verification testing, including compatibility of the device with the intended anatomy and all labeled accessories;
   (ii) Mechanical integrity and bond strength testing of the entire device, including all joints and component interfaces, under tensile and torsional forces expected during challenging clinical use conditions;
   (iii) Simulated use testing, including insertion, tracking, activation, and removal without device damage, to demonstrate that the device is able to function as intended under challenging clinical use conditions;
   (iv) Device visibility testing under standard imaging modalities;
   (v) Kink resistance when subjected to clinically relevant tortuosity;
   (vi) Delivery catheter functional testing. If the delivery catheter utilizes a balloon component the following must be demonstrated:
      (A) Balloon inflates and deflates within clinically relevant timeframes;
      (B) Balloon withstands rated burst pressure without failure;
      (C) Balloon withstands repeated inflation/deflation cycles without degradation; and
      (D) Balloon inflates uniformly, meeting labeled diameter and compliance specifications for stent deployment;
   (vii) Durability testing under clinically relevant mechanical stresses over time;
   (viii) Coating integrity and particulate testing of any coatings on the delivery catheter or stent; and
   (ix) Material stability testing, including *in situ* stability and resistance to degradation (e.g. corrosion, wear, delamination) of all device materials.

(4) All patient-contacting components of the device must be demonstrated to be biocompatible.

(5) All patient-contacting components of the device provided sterile must be demonstrated to be sterile and non-pyrogenic.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the established shelf life.

(7) Labeling must include:
   (i) A detailed summary of the device's technical parameters and materials;
   (ii) A summary of expected complications associated with the device; and
   (iii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the peripheral temporary and retrievable stent system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Luis Guardia at (240) 402-2912.

Sincerely,

Brian D. Pullin -S

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health