September 30, 2024

Vantis Vascular, Inc.
Angela Thompson
Vice President, Quality
2570 N First St., Suite 200
San Jose, California 95131

Re: K242276
Trade/Device Name: CrossFAST™ Integrated Microcatheter Guide Extension System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 1, 2024
Received: August 1, 2024

Dear Angela Thompson:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Samuel G. Raben -S

for Lydia Glaw
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242276

Device Name

CrossFAST™ Integrated Microcatheter Guide Extension System (CFM55)

Indications for Use *(Describe)*

The CrossFAST™ Integrated Microcatheter Guide Extension System is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

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.

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510(k) #: **K242276**

510(k) Summary

Prepared on: 2024-09-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vantis Vascular, Inc.
Applicant Address	2570 N First St. Suite 200 San Jose CA 95131 United States
Applicant Contact Telephone	510-673-0983
Applicant Contact	Angela Thompson
Applicant Contact Email	athompson@vantisvascular.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CrossFAST™ Integrated Microcatheter Guide Extension System (CFM55)
Common Name	Percutaneous catheter
Classification Name	Catheter, Percutaneous
Regulation Number	870.1250
Product Code(s)	DQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183353	Telescope™ Guide Extension Catheter	DQY

Device Description Summary

21 CFR 807.92(a)(4)

CrossFAST™ Integrated Microcatheter Guide Extension System (GES) ("Device" or "CrossFAST™ GES") is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices. It is intended for use in a cardiac catheterization laboratory by physicians trained in percutaneous, intravascular techniques and procedures.

CrossFAST™ GES consists of two catheters: an Inner Catheter and an Outer Catheter. The Outer Catheter is intended to act as an extension to a traditional guide catheter (i.e., "guide extension") and to facilitate delivery of interventional devices within the target vasculature. The Inner Catheter is intended to be pre-loaded into the Outer Catheter by the user and to provide additional support to the Outer Catheter during delivery. Once assembled, the Inner Catheter tip extends 4cm beyond the Outer Catheter tip. After the Outer Catheter has been delivered to the target vasculature, the Inner Catheter is removed from the Outer Catheter to allow for the passage of interventional devices.

The Device is designed for use in vessels larger than 2.5mm and is not for use in the neurovasculature or the venous system. The Device is single use and provided sterile via Ethylene Oxide (EO) sterilization. The Device is compatible with standard, off-the-shelf 0.014" lumen inner diameter (ID) and minimum 180cm length guidewires and a minimum 100cm length 6F guide catheters. The Device is intended for use with a hemostasis valve.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CrossFAST™ Integrated Microcatheter Guide Extension System is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Indications for Use Comparison 21 CFR 807.92(a)(5)

CrossFAST™ Integrated Microcatheter Guide Extension System GES ("CrossFAST™ GES") has the same intended use and Indications for Use as Telescope™ Guide Extension Catheter (K183353). Both devices are intended to be used in a cardiac catheterization laboratory by physicians trained in percutaneous, intravascular procedure. Both devices are for prescription use only. Both devices are similar in size and utilize radiopaque markers. Any differences between CrossFAST™ GES and Telescope Guide Extension Catheter (K183353) do not raise any different questions of safety and effectiveness as confirmed through the Performance Testing.

Technological Comparison 21 CFR 807.92(a)(6)

CrossFAST™ Integrated Microcatheter Guide Extension System GES ("CrossFAST™ GES") and Telescope Guide Extension Catheter (K183353) share the same or similar fundamental technological characteristics and principles of operation. Vantis Vascular, Inc. has performed comprehensive performance testing to demonstrate that the device meets all required specifications. The performance testing demonstrated that any technological differences between CrossFAST™ GES and Telescope Guide Extension Catheter (K183353) do not raise any different questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The technological differences between the subject and predicate device has been evaluated through design verification tests and biocompatibility tests to provide evidence of substantial equivalence for the CrossFAST™ GES. The following testing conducted is listed below.

Design Verification/In-Vitro (Bench) Testing:

1) Packaging/Transportation Testing
2) Visual and Dimensional Testing
3) Tensile Testing (including Simulated Use)
4) Performance Testing:
- System Preparation & Inspection Testing
- Stent Passage Testing (including Simulated Use)
- Catheter Kink Resistance Testing
- Catheter Torque Resistance Testing (including Simulated Use)
- Contrast Delivery Testing
- Radiopacity Testing

5) Track Force Testing (including. Simulated Use)
6) Particulate Testing (including Simulated Use)
7) Coating Characterization
- Baseline Coating Integrity
- Post Simulated Use Coating Integrity

Biocompatibility Testing:

1) Cytotoxicity
2) Sensitization
3) Irritation/Intracutaneous Toxicity
4) Acute Systemic Toxicity
5) Material Mediated Pyrogenicity
6) Hemocompatibility
- In-vivo Thromboresistance
- ASTM Hemolysis
- Complement Activation

7) Partial Thromboplastin Time

These tests confirmed that any technological differences between the proposed device and the selected predicate device does not raise different questions of safety or effectiveness. The test results support that the proposed device is at least as safe and as effective as the predicate device for the same intended use.

No clinical testing was conducted to support this 510(k) Premarket Notification. As such, this section is not applicable.

The tests demonstrated that the proposed device functions as intended for its proposed intended use and Indications for Use. These results further support that the proposed device performs at least as well as the predicate device for the same intended use and confirm that any technological differences do not raise different questions of safety or effectiveness.