November 22, 2021

Bacchus Vascular, Inc.
Anthony Sowunmi
Director, Quality Assurance And Regulatory Affairs
3110 Coronado Dr.
Santa Clara, California 95054

Re: K071664
Trade/Device Name: Trellis-6 Peripheral Infusion System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Anthony Sowunmi:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 13, 2007. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2021.11.22 13:35:00 -05'00'

Gregory O'Connell
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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Bacchus Vascular, Inc.
c/o Mr. Anthony Sowunmi
3110 Coronado Drive
Santa Clara, CA 95054

Re: K071664
Trade/Device Name: Trellis-6 Peripheral Infusion System
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II,
Product Code: KRA
Dated: June 15, 2007
Received: June 18, 2007

Dear Mr. Sowunmi:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volkmer

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application K071664

Device Name: Trellis-6 Peripheral Infusion System

Indications for Use:

The Trellis™-6 Peripheral Infusion System is intended for controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

Prescription Use X

(Part 21 CFR 801.109)

OR Over-The-Counter Use_____

(Optional Format 1-2-96)

PLEASE DO NOT WRITE BELOW THIS LINE -
(CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071664

K071664

510(k) Summary

Date Prepared

June 15, 2007

JUL 13 2007

General Information

Class	Class II
Trade Name	Trellis™-6 Peripheral Infusion System
Submitter	Bacchus Vascular, Inc 3110 Coronado Drive Santa Clara, CA 95054 Tel: 408-980-8300 Fax: 408-980-8383
Contact	Anthony Sowunmi Director, Quality Assurance and Regulatory Affairs

Intended Use

The Trellis™-6 Peripheral Infusion System is intended for controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature.

Predicate Device

Trellis-8 Infusion System K050147 Bacchus Vascular, Inc

Device Description

The Trellis-6 Peripheral Infusion System enables the physician to isolate a treatment region, infuse a physician-specified fluid, and disperse the fluid by means of oscillation of a Dispersion Wire. The Isolation/Infusion component is a multi-lumen catheter with two compliant balloons at the distal end and infusion holes located between these balloons. The device also has a central through-lumen that is compatible with a 0.035" guidewire. The Dispersion Wire provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit that oscillates the Dispersion Wire within the isolated region to further disperse the infused fluid. If desired by the physician, post procedure aspiration of the isolated area between the occluding balloons may be accomplished through the catheter by using the guidewire lumen.

Materials

All materials used in the manufacture of the Trellis-6 Peripheral Infusion System are suitable for this use and have been used in numerous previously cleared products.

Testing Summary

The Trellis-6 Peripheral Infusion System was tested in the same manner as the Trellis-8. All components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

The Trellis-6 Peripheral Infusion System is equivalent to the predicate product, the Trellis-8 Infusion System. The indications for use, function, methods of manufacturing, and materials used are substantially equivalent.