

K013635

**FEB 11 2002**

**510(k) Summary**

General Information

Classification	Class II
Trade Name	Trellis Infusion System
Submitter	Bacchus Vascular, Inc. 3110 Coronado Drive Santa Clara, CA 95054 408-980-8300
Contact	Greg Mathison Vice President, Clinical and Regulatory Affairs
Date Summary Prepared	February 1, 2002

Intended Use

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

Predicate Devices

<b>Dispatch Coronary Infusion Catheter</b> Manufactured by SCIMED Life Systems, Inc.	K932616
<b>Pulse*Spray Infusion System</b> Manufactured by AngioDynamics	K950907
<b>ISOLATE Infusion System</b> Manufactured by Lake Region, Inc.	K913517
<b>Squirt™ Fluid Delivery System</b> Manufactured by Merit Medical	K981417

Device Description

The Trellis Infusion Catheter 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. When inflated, the compliant balloons isolate a treatment zone to maintain concentration of the infused fluid. The device also has a central through-lumen that is compatible with a 0.035" guidewire. The Dispersion Wire component is a sheathed,

shape-set Nitinol cable that provides oscillation when activated. The Dispersion Wire is connected to an integral Oscillation Drive Unit which oscillates the Dispersion Wire up to 25 Hertz within the isolated region to further disperse the infused fluid.

### Materials

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

### Testing

The following testing was conducted to ensure the Trellis met all specifications:

- Tensile Testing
- Torque-to-Fail Testing
- Catheter Trackability and Dispersion Wire Insertion
- Guidewire Compatibility
- Balloon Compliance and Burst Testing
- Device and Battery Life Testing
- Catheter Leak Testing
- Infusion Flow Rates
- Catheter Corrosion Testing
- Electrical Safety and Electromagnetic Compatibility Testing

The results of the above tests demonstrated that the device is as safe & effective as the legally marketed predicate device. All components, subassemblies, and/or full devices met the required specifications for the above tests.

### Pre-clinical *in vivo* Testing

Testing of the Trellis and the predicate was conducted in animal arteries to assess acute safety, feasibility of introduction into the vascular system, the ability to visualize the devices under fluoroscopy, adverse reactions and/or device failures, and to examine acute histologic effects or injury to a normal vessel wall. Histological examination of treated vessels demonstrated that neither device caused serious injury to the vessel wall. Endothelial cell removal was greater in the predicate device than with the Trellis Infusion System.

### Summary of Substantial Equivalence

The Trellis is equivalent to the predicate products from SciMed, Merit Medical, AngioDynamics, and Lake Region. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Bacchus Vascular, Inc. believes the Trellis is substantially equivalent to existing legally marketed devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**FEB 11 2002**

Ms. Marybeth Gamber  
Regulatory Specialist  
Bacchus Vascular, Incorporated  
3110 Coronado Drive  
Santa Clara, CA 95054

Re: K013635  
Trade Name: Trellis Infusion System  
Regulation Number: 21 CFR 870.1210  
Regulation Name: Continuous Flush Catheter  
Regulatory Class: Class II (two)  
Product Code: KRA  
Dated: February 1, 2001  
Received: February 4, 2002

Dear Ms. Gamber:

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.

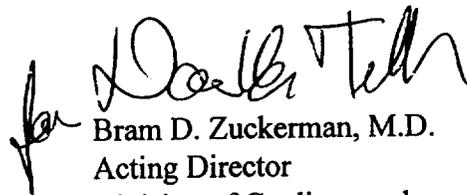
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

### Indications for Use

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

Device Name: Trellis Infusion System

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K013635

Prescription Use  OR Over-The-Counter Use   
(Per 21 CFR 801.109) (Optional Format 1-2-96)