

Guidant Corporation/ORIGIN
"Special 510(k): Device Modification"

VasoView™ Dissection/Vessel Harvesting System

K981700

Class II

MAY 29 1998

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

This 510(k) Summary details sufficient information to provide an understanding of the basis for a determination of substantial equivalence. For convenience, the summary is formatted pursuant to 21 CFR §807.92. This section may be used, as presented, to provide a substantial equivalence summary to anyone requesting it from the Agency.

21 CFR §807.92 a(1)

Submitter: Guidant Corporation ORIGIN® Medsystems, Inc.
135 Constitution Avenue
Menlo Park, CA 94025
(415) 617-5142
contact person: Cynthia G. Royster
date prepared: May 19, 1998

21 CFR §807.92 a(2)

Trade name: VasoView™ Dissection/Vessel Harvesting System

Common name: Dissection Cannula

Classification name: Distention Cannula

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the VasoView™ Dissection/Vessel Harvesting System is based on its similarities to predicate device : the ORIGIN System VasoView™ Balloon Dissection System. It shares similar material, and identical technological characteristics as the predicate device. It also is identical in intended use.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: The VasoView™ Dissection/Vessel Harvesting System is a single-use device provided sterile. It is designed to be used in conjunction with a 5mm Extended Length Endoscope. The cannula has a tapered tip for tissue separation. Initial tissue separation is performed under endoscopic visualization with the clear tapered tip. The elliptical bulb aids tissue separation, and insufflation holds open the cavity created.

The cannula tip may also be used for dissection and isolation of structures in the cavity. This tip is clear to allow for endoscopic visualization during tunneling. A handle is provided to assist with advancement of the cannula.

K481100

Guidant Corporation/ORIGIN
 "Special 510(k): Device Modification"

VasoView™ Dissection/Vessel Harvesting System

Class II

The device is configured to accept a 5mm endoscope through the inner lumen of the cannula.

The Origin BTT Port is used to provide a port of access for insertion of endoscopic instruments into an extremity or extraperitoneal space. The device consists of a valve body assembly with a balloon on the sleeve. The valve body assembly contains an internal flapper valve and seal to prevent gas leakage when instruments are inserted or withdrawn. It also includes built-in converter doors to allow insertion of instruments of different diameters than the main seal. The external distal end of the sleeve has a balloon. A 30cc syringe is provided for inflation/deflation of the balloon.

Device Description-materials/physical properties: a table of the patient contact components, with their respective materials, is provided below.

Component Name	Patient Contact	Material	Predicate
Cannula	yes	Polycarbonate	Vaso View Balloon Dissection Cannula K964171
Elliptical Bulb	yes	Polycarbonate	Vaso View Balloon Dissection Cannula K964171
Adhesive	yes	Loctite™	Vaso View Balloon Dissection Cannula K964171
Manifold	yes	Polycarbonate	Vaso View Balloon Dissection Cannula K964171

The listed parts are currently being used in existing ORIGIN products, and therefore have been cleared for biocompatibility (safety) and effectiveness.

K981700

Guidant Corporation/ORIGIN
"Special 510(k): Device Modification"

VasoView™ Dissection/Vessel Harvesting System

Class II

21 CFR §807.92 a(5)

Intended use and relationship to predicate(s): **The VasoView™**

Dissection/Vessel Harvesting System has applications in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients undergoing endoscopic surgery requiring tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/ vessel harvesting along the saphenous vein and the femoral vessels.

Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

The The VasoView™ Dissection/Vessel Harvesting System is not intended for use except as indicated. In addition, it is not intended for use when endoscopic surgery is contraindicated.

CFR §807.92 a(6)

Technological characteristics and relationship to predicate(s):

The VasoView™ Dissection/Vessel Harvesting System is substantially equivalent to the Vaso View Balloon Dissection Cannula previously cleared product. The VasoView™ Dissection/Vessel Harvesting System shares the identical function, technological characteristics and similar materials as the predicate device.

21 CFR §807.92 b

This submission's determination of substantial equivalence is based on similarities to the predicate devices in terms of intended uses, materials, and technological characteristics.

21 CFR §807.92 c

In accordance with the specifications of this subsection, this summary (3 pages) is its own section, and has been clearly identified as such.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

Ms. Cynthia G. Royster
Manager
Regulatory Affairs
ORIGIN Medsystems, Incorporated
135 Constitution Drive
Menlo Park, California 94025

Re: K981700
Trade Name: Vaso-View™ Dissection/Vessel Harvesting
System
Regulatory Class: II
Product Code: GCJ
Dated: May 5, 1998
Received: May 14, 1998

Dear Ms. Royster:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

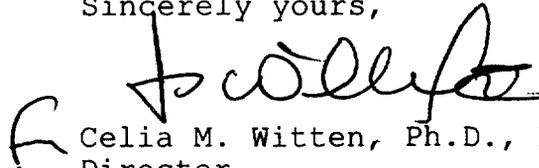
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Royster

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K981100

K981700

510(k) Number (if known): K964171

Device Name: VasoView™ Balloon Dissection System

Indications For Use: **has applications in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic vessel harvesting for arterial bypass. It is indicated for patients undergoing endoscopic surgery requiring tissue separation of the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein and the femoral vessels. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X [Signature] The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices K981700
510(k) Number _____

4016