

510(k) Summary

510(k) Summary as required by section 807.92(c)

K100518

AUG 31 2010

date prepared 8/16/2010

Submission Applicant:

INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Establishment Registration Number:

1421101

Official Correspondent:

Mr. Berndt Fetzer
INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Phone: 847-908-0292

Trade name:

Instrumed Vessel Dilators

Common name:

Various Vessel Dilators:
Cooley Coronary Vessel Dilators, Garrett Vascular Dilators, DeBakey Vascular Dilators

Classification name:

21 CFR	MEDICAL DEVICES
PART 870 --	CARDIOVASCULAR DEVICES --
Subpart E--	Cardiovascular Surgical Devices

Sec. 870.4475	Surgical vessel dilator.	Code DWP
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Regulation Description

A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

Substantial Equivalence Claims:

K030788	KAMAR ANNULUS DILATOR + SIZER; GARRETT, COOLEY, AND DEBAKEY VESSEL DILATORS
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Applicant	GEISTER MEDIZINTECHNIK GMBH
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Description of the Device:

Instrumed Vessel Dilators are reusable surgical instruments.

To ensure the multi-purpose use of this device, different models are available. The differences can be in length, diameter, and design of the dilators

Dilators are used

- to check patency of vessel in coronary artery bypass procedures
- to check patency of other vessels in pheripheral vascular procedures
- olive shaped tips (Garrett)

The surgeon chooses the instrument based on the anatomy of the vessel and the type desired, and on the type of the surgical procedure.

Instrumed Vessel Dilators are made of ASTM F 899-07 standardized Stainless Steel.
The instruments are offered in non-sterile condition.

Indications for Use:

INSTRUMED vessel dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various manoeuvres of dilation and measurement of annulus and lumen diameters

Comparison with Predicate Device:

Performance characteristics that have been evaluated for the Instrumed Vessel Dilators through testing performed on the proposed device and testing leveraged from previously cleared devices; including the following technological characteristics:

- Design
 - Simulated Use
 - Clinical evaluation
 - market surveillance data
 - Dimensional Verification
 - Dilator tip diameter
 - Dilator length
 - Tip length
 - Wire diameter
 - visual inspection
 - Dilator surface free from defects
 - Wire surface free from defects
 - mechanical testing
 - Test of distal tip retention
 - Wire to handle joint strength
- Material
 - material certificates
 - material analysis
 - mechanical strength
 - corrosion testing
 - Test of corrosion resistance
 - biocompatibility
 - cytotoxicity effects

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The results of non-clinical and bench testing indicate that the new devices are completely comparable to the predicate devices.

Results of clinical evaluation based on literature research and market surveillance information from

- database evaluation
- Information from scientific literature
- data from market experience of the same or similar devices

has proven that the design is safe and effective.

Instrumed International has provided hundreds of dilators in the last 5 years to customers supporting other than US markets, without any reported customer complaint or potentially reportable event.

The Instrumed Vessel Dilators are substantially equivalent to the predicate devices in terms of

- technical characteristics
- design
- Indications for Use
- Target population
- where it is used
- performance
- biocompatibility
- sterilization method
- mechanical safety characteristics
- as well as sizes and configurations.

Conclusion:

The presented data that was conducted on the Instrumed Vessel Dilators shows in its results and in comparison to the predicate devices that the products are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Instrumed International, Inc.
c/o Mr. Michael Massong
QA/RA Director
626 Cooper Court
Schaumburg, IL 60173

AUG 31 2010

Re: K100518
Trade/Device Name: Instrumed Vessel Dilators
Common Name: Dilator, Vessel, Surgical
Regulation Number: 21 CFR 870.4475
Regulatory Class: II
Product Code: DWP
Dated: August 19, 2010
Received: August 25, 2010

Dear Mr. Massong:

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. 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.

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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.

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 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOFFices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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): K100518

Device Name: Instrumed Vessel Dilators

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashtley Bow
(Division Sign-Off)
Division of Cardiovascular Devices

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