K020879 page 1/2

Integrated Vascular Systems, Inc.

SEP 25 2002

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C. F.R. § 807.92.

Submitted by:	Susan Turner, Ph.D. Director, Regulatory Affairs & Quality Assurance Integrated Vascular Systems, Inc. 743 N. Pastoria Ave. Sunnyvale, CA 94085 Telephone: (408) 328-9090 Fax: (408) 328-9099	
Date prepared:	July 2, 2002	
Device name:	IVS Clip Closure System	
Common name:	Clip, clip applier, catheter introducer	
Classification names:	**Regulation # and Product Code**	**Classification Name**
	21 C.F.R. § 878.4300 FZP	Implantable clip
	21 C.F.R. § 870.1340 DYB	Catheter introducer
Predicate devices:	The IVS Clip Closure System is substantially equivalent to the Angiolink EVS™ Vascular Closure System.	
Device description:	The IVS Clip Closure System consists of an extravascular implantable nitinol clip mounted on an Introducer Sheath. A clip applier acts to release the clip into vascular tissue where it closes vascular puncture wounds.	
Indication for Use:	The IVS Clip Closure System is intended for use to approximate vascular tissue for achieving hemostatic closure of puncture sites to aid healing in minimally invasive procedures under direct or endoscopic visualization.	

Technological characteristics:	The subject and predicate devices have the same intended use and principles of operation. Both systems stabilize the site, guide and center on the wound and deliver a clip/staple to the wound site for tissue approximation and immediate mechanical extravascular closure. The IVS systems uses a nitinol clip; the EVS system uses a titanium staple. The clip applier and stapler are both manually operated although the mechanisms are different. Performance testing of the IVS system demonstrates that there are no new issues of safety or effectiveness associated with this difference. The IVS implantable clip is mounted on an Introducer Sheath. The sheath is a standard 6 French sheath and performance testing demonstrates that there are no new issues of safety or effectiveness associated with the presence of the clip/clip carrier assembly on the catheter introducer.
Testing:	The IVS Clip Closure System has been tested *in vitro*, *in vivo* and in human model systems. Test results show that the device is safe and effective for the intended use. All components which contact the fluid path or tissue are biocompatible in accordance with ISO Standard 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2003

Susan Turner, Ph.D.
Director, Regulatory Affairs & Quality Assurance
Integrated Vascular Systems, Inc.
743 North Pastoria Avenue
Sunnyvale, California 94085

Re: K020879
Trade/Device Name: IVS Clip Closure System, Model 1002 and IVS Introducer Set
Regulation Number: 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: July 2, 2002
Received: July 2, 2002

Dear Dr. Turner:

This letter corrects our substantially equivalent letter of September 25, 2002 regarding the IVS Clip Closure System, which failed to include the IVS Introducer Set.

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 (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 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 continue 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

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

Indications For Use Statement
Revised July 2, 2002

510(k) Number (if known) **K020879**

Device Name The IVS Clip Closure System.

Indications For Use The IVS Clip Closure System is intended for use to approximate vascular tissue for achieving hemostatic closure of puncture sites to aid healing in minimally invasive procedures under direct or endoscopic visualization.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR § 801.109)

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020879