Acta Vascular

JUN 1 - 2005

IV. 510(k) Summary

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

A. Date Prepared

August 12, 2004

B. General Information

Manufacturer: Acta Vascular Systems, Inc.
247 Marchmont Drive
Los Gatos, CA 95032

Contact: Richard M. Ruedy
Vice President, Regulatory and Clinical Affairs and Quality Systems
(408) 828-7281 phone
(408) 748-1642 fax

C. Device Information

Common, Usual or Classification Name:	Artificial Embolization Device
Device Classification:	III
Product Code:	HCG
Classification Regulation:	21 CFR §882.5950

D. Predicate Device Identification

Product (Trade Name)	**Manufacturer**	**510(k) Premarket Notification Number and Date**	**Intended Use**
Contour PVA Particles	Interventional Therapeutics/Target Therapeutics/Boston Scientific	K944354 December 13, 1994	This device is intended for embolization of hypervascular tumors and arteriovenous malformations.

Contour PVA Particles are available in the following configurations†:

Order No.	**Particle Size (µm)**
760012	45 –150
760022	150 - 250
760032	250 - 355
760042	355 - 500
760062	500 - 710
760082	710 -1000
760112	1000 -1180

† Particle sizes were obtained from the Product Information sheet published by the manufacturer.

E. Intended Use

Ultra IVALON and Ultra DRIVALON PVA Embolization Particles are intended for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

F. Product Description

Ultra IVALON and Ultra DRIVALON PVA Embolization Particles are artificial embolization devices used for permanent embolization of hypervascular lesions and arteriovenous malformations (AVMs) via superselective catheter delivery. The embolization particles are supplied in various size ranges to enable appropriate size selection for the lesion to be treated. Ultra IVALON and Ultra DRIVALON PVA Embolization Particles are designed to be delivered under fluoroscopic guidance through compatible infusion/delivery catheters.

Ultra IVALON PVA Embolization Particles are suspended in 0.9% saline (NaCl) solution. Ultra DRIVALON PVA Embolization Particles are packaged in a dry form. Each unit contains 0.1g of particles.

Catalog Number	Size Range	Compatible Catheter Inner Diameter
UI001 and UD001	50 - 150 µm	0.018"
UI002 and UD002	150 - 250 µm	0.018"
UI003 and UD003	250 - 400 µm	0.018"
UI004 and UD004	400 - 600 µm	0.025"
UI005 and UD005	600 - 1000 µm	0.044"

G. Substantial Equivalence

The subject device is equivalent in intended use, design, and technological characteristics to the predicate devices listed above.

H. Non-clinical Test Results

Testing has shown the subject device to be safe and effective for its intended use.

I. Summary

Based on the information provided in this notification, the subject device is substantially equivalent to the predicate devices in intended use, technological characteristics, and design.

J. Signature of Preparer

Richard M. Ruedy
Vice President, Regulatory and Clinical Affairs and Quality Systems
Acta Vascular Systems, Inc.

Section VI. Device Description
Appendix I
Section VII. Comparative Information
Appendix II.
Section VIII. Biocompatibility Assessment
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Section IX. Sterilization Information
Section V. Proposed Labeling
Section X.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

Mr. Richard M. Ruedy
Vice President, Regulatory and Clinical Affairs and Quality Systems
Acta Vascular Systems Incorporated
247 Marchmont Drive
Los Gatos, California 95032

Re: K042297
Trade/Device Name: Ultra IVALON and Ultra DRIVALON PVA Embolization Particles
Regulation Number: 21 CFR 882. 5950
Regulation Name: Artificial embolization device
Regulatory Class: II
Product Code: HCG, KRD
Dated: March 30, 2005
Received: April 1, 2005

Dear Mr. Ruedy:

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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042297

III. Statement of Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: Ultra IVALON and Ultra DRIVALON PVA Embolization Particles

Indications for Use:

Ultra IVALON and Ultra DRIVALON PVA Embolization Particles are intended for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

K042297