DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

The Wallace Enterprises, Inc.
DBAVascular Architects
% Mr. Kevin F. MacDonald
Regulatory Consultant
229 Marvilla Circle
Pacifica, California 94044

Re: K012544
Trade/Device Name: Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: II
Product Code: JCT
Dated: October 26, 2001
Received: October 31, 2001

Dear Mr. MacDonald:

This letter corrects our substantially equivalent letter of November 15, 2001.

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.

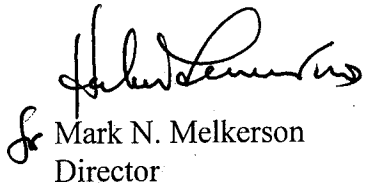
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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), 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**Indications for Use**

| | |
|---|---|
| 510(k) Number (if known): | K012544 |
| Device Name: | Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System |
| Indications for Use: | The Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System are indicated for use in the treatment of tracheobronhial strictures produced by malignant neoplasms. |

Prescription Use ___X___ OR Over-The-Counter Use_____

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)

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

**510(k) Number** K012544

**510(k) Summary of Safety and Effectiveness**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is **K012544.**

General Information

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|---|---|
| Date Amended: | July 28, 2006 |
| Classification | Class II, Tracheal Prosthesis per 21 CFR § 878.3720 |
| Product Code | JCT |
| Common Name: | Tracheal Stent |
| Trade Name | Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System |
| Submitter | Wallace Enterprises, Inc. DBA Vascular Architects<br>1650 Elm Hill Pike<br>Nashville, TN 37210 |
| Contact | Kevin F. MacDonald<br>Regulatory Consultant<br>Tel. 415 609 9875 |

Intended Use

The Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System are indicated for use in the treatment of tracheobronhial strictures produced by malignant neoplasms.

Predicate Devices

K003173 – Vascular Architects aSpire® Covered Stent and Delivery Catheter

Device Description

The Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System is designed to increase the luminal diameter within tracheobronhial strictures produced by malignant neoplasms.

Comparison To Predicate Device

The Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System has a similar intended use and shares the same technological characteristics as the predicate device.

The Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System are well-characterized materials and are suitable for this use. The materials are similar to those used to manufacture the predicate device.

The available lengths and diameters of the Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System are similar to the lengths and diameters available for the predicate device.

Testing Summary

Simulated use and performance testing was conducted on the Vascular Architects aSpire® Covered Stent and Controlled Expansion® Delivery System. Results of the bench testing performed demonstrate the mechanical integrity and device performance of the subject device are substantially equivalent to that of the predicate device.