K080838
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14 510(k) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Per 21 CFR 807.92)

APR 24 2008

General Company Information

Name: Alveolus, Inc.
Contact: Tony Alexander
EVP Corporate Compliance

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Charlotte, NC 28216

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Date Prepared: March 24, 2008

General Device Information

Product Name: ALIMAXX-E™ Esophageal Stent System

Classification: "Esophageal Prosthesis", Product code: ESW
21 CFR 878.3610 - Class II

Predicate Device

Alveolus ALIMAXX-E™ Esophageal Stent System [510(k) Number K051621]

Description

The Alveolus ALIMAXX-E™ Esophageal Stent System is designed to maintain lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors. The stent is also indicated for occlusion of esophageal fistulae.

The Alveolus ALIMAXX-E™ Esophageal Stent System is comprised of two components: the completely covered, self-expanding Nitinol stent and the delivery system. The ALIMAXX-E™ Esophageal Stent System is available in several diameters and lengths.

The single-patient-use components of the ALIMAXX-E™ Esophageal Stent System are provided non-sterile.

Intended Use (Indications)

The Alveolus ALIMAXX-E™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors. The stent is also indicated for occlusion of esophageal fistulae.

Substantial Equivalence

This Notice supports the position that the modified Alveolus ALIMAXX-E™ Esophageal Stent is substantially equivalent to the Alveolus ALIMAXX-E™ Esophageal Stent System [510(k) Number K051621].

Comparisons of the modified Alveolus ALIMAXX-E™ Esophageal Stent System and the ALIMAXX-E™ Stent System predicate device (K051621) show that technological characteristics such as materials, biocompatibility, performances properties, sterilization and packaging are substantially equivalent to the currently marketed predicate device. Physical test results were performed and biocompatibility test results included tests recommended in FDA "Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses" (issued on April 28, 1998).

Conclusions

Alveolus believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the subject device. The materials from which the Alveolus device is fabricated have an established history of use in clinical applications, and the devices produced by Alveolus have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 24 2008

Mr. Tony Alexander
Chief Legal Officer
Alveolus®, Inc.
9013-A Perimeter Woods Drive
CHARLOTTE NC 28216

Re: K080838
Trade/Device Name: ALIMAXX-E™ Esophageal Stent System
Regulation Number: 21 CFR §878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: March 24, 2008
Received: March 25, 2008

Dear Mr. Alexander:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K080838

1 INTENDED USE STATEMENT

There are no changes in the Intended Use.
The Intended Use for the Subject Device is the same as the Intended Use for the ALIMAXX-E™ predicate system (K051621).

Device Name: Alveolus, ALIMAXX-E™ Esophageal Stent System

Indications for Use:

The Alveolus ALIMAXX-E™ Esophageal Stent System is intended for maintaining esophageal lumen patency in esophageal strictures caused by intrinsic and / or extrinsic malignant tumors and for occlusion of esophageal fistulae.

Prescription Use___X___ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K080838