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15.510K SUMMARY

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

General Company Information

Name:	Alveolus, Inc.
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Date Prepared: September 24, 2007

General Device Information

Product Name:	ALIMAXX-B™ Uncovered Biliary Stent System
Classification:	"Biliary Catheter and Accessories" Product code: FGE 21 CFR 876.5010 – Class II

Predicate Devices

This Notice supports the position that the ALIMAXX-B Uncovered Biliary Stent is substantially equivalent to previously cleared devices, including the Bard® LUMINEXX™ Biliary Stent and Delivery Catheter cleared by FDA under 510(k) number K031186, and the Cook® Zilver™ Biliary Stent cleared by FDA under 510(k) number K020788, and the Absolute™ Biliary Self-Expanding Stent cleared by FDA under 510(k) number K033393.

Description
The ALIMAXX-B Uncovered biliary stent is a sterile, single-use, self-

expanding Nitinol stent that is supplied with the stent pre-loaded on the delivery catheter. The delivery device is available for endoscopic placement (working length is 185 cm), and transhepatic placement (working length 80 cm).

Intended Use (Indications)

The stent is indicated for palliation of malignant neoplasms in the biliary tree.

Substantial Equivalence

This Notice supports the position that the ALIMAXX-B Uncovered Biliary Stent is substantially equivalent to previously cleared devices, including the Bard® LUMINEXX™ Endoscopic Biliary Stent cleared by FDA under 510(k) number K031186, and the Cook® Zilver™ Biliary Stent cleared by FDA under 510(k) number K020788, and the ABSOLUTE™ .035 Biliary Self-Expanding Stent cleared by FDA under K033393.

This 510(k) Notice contains summaries of physical test results for the delivery system as specified in the FDA "Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents" document (February 5, 1998).

The data presented demonstrate that the device is suitable for its indicated use.

The ALIMAXX-B Uncovered Biliary Stent System is provided sterile and for single use only.

Conclusions

In summary, Alveolus has provided the required tests, assessments, and comparisons to demonstrate that the Alveolus ALIMAXX-B Biliary Stent System is substantially equivalent to the above referenced predicate devices in terms of composition, design, intended use and performance attributes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2008

Mr. Tony D. Alexander
Exec. VP, Chief Legal Officer & Corporate
Secretary, Quality Executive
Alveolus™, Inc.
9013 Perimeter Woods Drive, Suite A
CHARLOTTE NC 28216

Re: K072720
Trade/Device Name: Alveolus, ALIMAXX-B™ Uncovered Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: January 11, 2008
Received: January 14, 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

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.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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/dsma/dsmamain.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.H.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K072720

Device Name: Alveolus, ALIMAXX-B™ Uncovered Biliary Stent System

FDA's Statement of the Indications for Use for device:

The Alveolus, ALIMAXX-B™ Uncovered Biliary Stent System is intended for palliation of malignant strictures in the biliary tree.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K072720