K072749

MAY 14 2008

510(K) SUMMARY

SIALOTECH DILATION BALLOON KIT AND ACCESSORIES

510(k) Number K_____

Applicant's Name: Sialo Technologies Ltd.
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Date Prepared: August 2007

Trade Name: Sialo Dilatation Balloon Catheter (for salivary duct)

Classification Name: CFR Classification section 876.1500 (Product code GCJ)

Classification: Class II medical Device

Predicate Device: The Sialo Balloon Dilatation Catheter device is comparable to the following predicate devices:

- The Salivary Duct Dilator (Class I 510(k) exempt device) manufactured by Cook Medical. The salivary duct dilator is a rigid rod with known diameter, which is inserted into the salivary duct to create mechanical dilatation.
- The accessories of KSEA Sialoendoscope and accessories (K012527) manufactured by Karl Storz Endoscopy. KSEA Sialoendoscope is an endoscopic device with accessories intended to treat salivary gland disease.

- The Ascend™ Balloon Dilatation Catheter (K970041) manufactured by Cook Urological.

Device Description: Sialo Balloon Dilatation Catheter is designed to allow dilatation of the salivary duct under endoscopic or radiological guidance. Dilatation can be therapeutic by itself (for duct strictures), or provide endoscopic access for stone removal.

Intended Use / Indication for Use: The Sialo device is a medical device for use by qualified surgeons in the treatment of salivary gland diseases.

Performance Standards: None.

Test Data: The Sialo Balloon dilatation device has been subjected to extensive safety, performance, and validation testing before release. Final testing of the Sialo device included various performance tests designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards. Literature review describing device use in other countries is provided in Section 21 of this submission.

Substantial Equivalence: The Sialo Balloon dilatation device is similar to currently distributed endoscopic accessory devices intended for treatment of other strictures in other body cavities; and it is similar in intended use to the Cook salivary duct dilator. Dilatation balloon catheters are used through endoscopic working channels to dilate a variety of ducts/ tubes, such as dilatation balloons for the biliary duct, for the urinary tract, for the lacrimal duct, and for dilatation of blood vessels. All of the above features are similar to these features in the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices, is that the Sialo Balloon dilatation device is substantially equivalent in safety and efficacy to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2008

Sialo Technologies Limited
C/O Ms. Ahava Stein
Regulatory Affairs Consultant
A. Stein Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
ISRAEL

Re: K072749
Trade/Device Name: Sialo Dilatation Balloon Catheter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 9, 2008
Received: April 17, 2008

Dear Ms. Stein:

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.

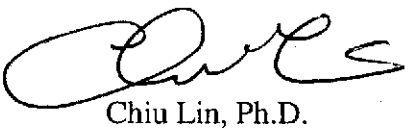
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
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Enclosure

K072749

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Sialo Dilatation Balloon Catheter

Intended Use Statement:
The Sialo Balloon dilatation catheter is a medical device for use by qualified surgeons in the treatment of salivary gland diseases.

Prescription Use __√___ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use___ (Optional Format 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 Anesthesiology, General Hospital
Infection Control, Dental Devices

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