MAR 1 3 2009

510(K) SUMMARY

SIALOTECH MODULAR STONE GRASPING BASKET

510(k) Number K082735

Applicant's Name: Sialo Technology Ltd.
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Date Prepared: September 14, 2008

Trade Name: Sialo Stone Grasping Basket

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

Classification: Class II medical Device

Predicate Device: The Sialo Modular Stone Grasping Basket device is comparable to the following predicate devices:

- Stone basket of KSEA Sialoendoscope (K012527) manufactured by Karl Storz Endoscopy.
- Stone Basket for Midiview series (K051073) manufactured by Millennium Devices Inc.
- Wittich Nitinol Stone Basket (K902944) manufactured by Cook Inc

Device Description: The stone grasping basket is a 30mm long, 4 wire, 10mm Nitinol Stone removal Basket, which is designed to pass through low diameter working channels of endoscopes for the purpose of retrieval of stones from the salivary gland.

Intended Use / Indication for Use:

The Stone Grasping Basket is a medical device indicated for use by qualified surgeons in the treatment of salivary gland diseases. It is used endoscopically to entrap and remove mobile stones and stone fragments smaller than 5mm from the salivary gland.

Performance Standards: None.

Test Data: The Stone Grasping Basket device has been subjected to safety and performance testing before release. Testing of the device included various performance tests designed to ensure that the device meets all its functional specifications and complies with safety standards.

Substantial Equivalence:

The Sialo Stone Grasping Basket device is similar to the currently distributed endoscopic accessory devices intended for stone removal, such as the basket accessory of the Karl Storz KSEA Sialoendoscope (K012527), the stone basket of Midiview series (K051073) manufactured by Millennium Devices Inc. and the Wittich Nitinol Stone Basket (K902944).

The device has the same intended use and uses the same basic technology as the predicate devices.

The results of the performance tests demonstrate that the stone grasping basket meets its specifications for efficacy and exhibits similar physical properties as the predicate devices.

Conclusions: The conclusions drawn from the above Performance Testing and comparison to predicate devices, is that the Sialo Stone Grasping Basket device is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 3 2009

Sialo Technologies Ltd.
c/o Ms. Ahava Stein
General Manager, A. Stein – Regulatory Affairs Consulting Ltd.
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba, Israel

Re: K082735
Trade/Device Name: Stone Grasping Basket
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 25, 2009
Received: March 3, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082735

Device Name: Sialo Stone Grasping Basket

Intended Use Statement:

The Stone Grasping Basket is a medical device indicated for use by qualified surgeons in the treatment of salivary gland diseases. It is used endoscopically to entrap and remove mobile stones and stone fragments smaller than 5mm from the salivary gland.

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 Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K082735