



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

September 3, 2015

Cosmo Technologies Ltd.  
% Steve Kradjian  
Conventus Biomedical  
5414 Oberlin Drive, Suite 130  
San Diego, CA 92121

Re: K150852  
Trade/Device Name: SIC 8000  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: PLL  
Dated: August 1, 2015  
Received: August 3, 2015

Dear Steve Kradjian,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joyce M. Whang -S**

for Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

To be determined  
K150852

Device Name

SIC 8000 Submucosal Injection Composition

Indications for Use (Describe)

The SIC 8000 is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## **SECTION 5.0**

### **510(k) SUMMARY**

**5.0 510(k) Summary for the SIC 8000****5.1 Submission Sponsor:**

Cosmo Technologies Ltd.  
42-43 Amiens Street, Dublin 1 – Ireland  
Telephone: +353 (1) 8170370  
Fax: +353 (1) 8230718  
FDA Establishment Registration #: the facility is not currently registered

**5.2 Submission Correspondent:**

Steven A. Kradjian  
President, Conventus Biomedical Solutions, Inc.  
U.S. Agent and Authorized Representative for Cosmo Technologies, Ltd.  
5414 Oberlin Drive, Suite 130  
San Diego, CA 92121  
Tel: (858) 401-2111  
Email: [skradjian@conventusbiomed.com](mailto:skradjian@conventusbiomed.com)

**5.3 Date Prepared:**

31 March 2015, Amended 03 September 2015

**5.4 Device Name:**

Trade/Proprietary Name:	SIC 8000
Common Name:	GI Endoscopic Injection Needle
Classification Name:	GI Endoscopic Injection Needle
Product Code:	<del>TBD</del> PLL
Regulation Number:	876.1500
Device Class:	II
Review Panel:	Gastroenterology and Urology

**5.5 Substantial Equivalence:**

SIC 8000 is substantially equivalent in terms of both intended use and technological characteristics to the Cook GI Endoscopic Injection Gel Kit, which was cleared for marketing under K111495 on 19 July 2011 for sub mucosal lift of polyps or other gastrointestinal mucosal lesions, prior to excision with a snare or endoscopic device.

**5.6 Device Description:**

SIC 8000 is an injectable liquid composition in the form of an oil-in-water (o/w) emulsion for use as a submucosal injection agent during endoscopic mucosal resection (EMR), endoscopic mucosal dissection (ESD) and polypectomy procedures in the gastrointestinal tract. The device is intended for use in endoscopic resection procedures in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the small intestine, the colon, the sigmoid colon, and the rectum, as a submucosal injectable agent during the removal of polyps, adenomas, early-stage cancers and other pathological lesions by EMR, ESD or polypectomy. SIC 8000 is injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope. The emulsion, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform an easy and safe resection procedure (EMR, ESD or polypectomy).

**5.7 Indications for Use:**

SIC 8000 is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.

**5.8 Performance Data:**

A series of performance tests and animal studies were conducted which demonstrated the quantitative mechanical performance, tolerance and usability of SIC 8000 in endoscopic procedures.