DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 8, 2016

Salvin Dental Specialties
c/o John Kapitan
President
Kapstone Medical
100 E. South Main St., PO Box 1458
Waxhaw, North Carolina 28173

Re: K160493
Trade/Device Name: Salvin CytoSurg™ Non-Resorbable PTFE Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPK
Dated: August 8, 2016
Received: August 11, 2016

Dear John Kapitan:

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" (21 CFR 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K160493

Device Name: Salvin CytoSurg™ Non-Resorbable PTFE Membrane

Indications for Use:

The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is a temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary K160493

1. Applicant

Salvin Dental Specialties, Inc.
3450 Latrobe Drive
Charlotte, NC 28211

Date Prepared: September 7, 2016

Contact Person: John Kapitan
Tel: (704) 516-5120
Email: jkapitan@kapstonemedical.com

2. Device Name

Proprietary Trade Name: Salvin CytoSurg™ Non-Resorbable PTFE Membrane
Common/Usual Name: PTFE Barrier Membrane
Classification Name: Bone grafting material
Regulation Number: 21CFR872.3930
Product Code: NPK
Classification: II
Panel: Dental

3. Predicate Devices

The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is substantially equivalent to the Cytoflex® Non-Resorbable Barrier Membrane, produced by Unicare Biomedical.

Comparison Table

Applicant	**Salvin Dental**	**Unicare Biomedical**
Product Name	**CytoSurg™ Non-Resorbable PTFE Membrane**	**Cytoflex® Non-Resorbable Barrier Membrane**
510(k) Number	K160493	K012144
Product Code	NPK	NPK
Regulation #	21CFR872.3930	21CFR872.3930
Class	II	II
Prescription or O-T-C?	Prescription	Prescription
Provided Sterile or Non-sterile?	Sterile	Sterile
Indications for Use	The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is a temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.	Cytoflex® is a temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.
Components and Size(s)	*250 micron thickness*	*250 micron thickness*

Applicant	Salvin Dental	Unicare Biomedical
Product Name	**CytoSurg™ Non-Resorbable PTFE Membrane**	**Cytoflex® Non-Resorbable Barrier Membrane**
	25mm x 30mm *12mm x 24mm*	*25mm x 30mm*
Device/Implant Materials	ePTFE	ePTFE
Sterilization Methodology	ETO	ETO

4. Description of the Device

The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is composed of microporous PTFE material. It has a nominal thickness of 250 microns and is supplied in two sizes (25mm x 30mm and 12mm x 24mm). The membranes are single use and are supplied in sterile sealed pouches.

5. Indications for Use

The Salvin CytoSurg™ Non-Resorbable PTFE Membrane is a temporarily implantable material (non-resorbable) for use as a space-making barrier in the treatment of periodontal defects.

6. Technology Characteristics

The technological characteristics of the Salvin CytoSurg™ Non-Resorbable PTFE Membrane are equivalent to the predicate device. The subject and predicate devices have the same design including the same material, fiber size, and membrane thickness.

7. Summary of Performance Data

Specific Tests Performed: Tensile Strength
Tear Resistance
ISO 10993-5 / Tests Cytotoxicity
ISO 10993-6 / Tests Local Effects After Implantation
ISO 10993-10 / Tests for irritation and skin sensitization
ISO 10993-11 / Tests for Systemic Toxicity
Packaging Validation
Sterilization Validation

Bench testing including tensile strength and tear resistance, as well as geometric comparisons of the Salvin Cytosurg™ device to the Unicare Biomedical Cytoflex® device demonstrated substantial equivalence. The results for Biocompatibility Testing, Packaging Validations and Sterile Validation met their acceptance criteria.

7. Conclusion

The Salvin CytoSurg™ Membrane is substantially equivalent to the Unicare Biomedical Cytoflex predicate device (K012144). In addition to conclusions from performance testing and geometric comparisons, the devices have the same "Indications for Use," are available by prescription only, utilize ePTFE material, and are provided sterile for single-use only. It can be concluded that the Salvin CytoSurg™ Membrane is substantially equivalent to the predicate device.