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

October 12, 2016

Synergetics
Mr. Dan Regan
Regulatory Affairs Director
3845 Corporate Centre Drive
O' Fallon, Missouri 63368

Re: K160103
Trade/Device Name: Spetzler Malis Dual Illuminating Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 7, 2016
Received: September 9, 2016

Dear Mr. Regan:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160103

Device Name
Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Indications for Use *(Describe)*

The Spetzler™-Malis® Dual Illuminating Bipolar Forceps are designed for use with the Malis® Bipolar electrosurgical generators. The disposable Spetzler™-Malis® Dual Illuminating Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue and to supply light for surgical procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

I. SUBMITTER

Applicant's Name and Address:	Synergetics 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Dan Regan, Regulatory Affairs Director
Date Prepared:	October 11, 2016

II. DEVICE

Device Trade Name:	Spetzler™ Malis® Dual Illuminating Bipolar Forceps
Common Name:	Illuminating Bipolar Forceps
Device Classification:	21 CFR Part 878.4400, Electrosurgical Cutting and Coagulation Devices and Accessories are Class II devices.
Class Name:	Electrosurgical, Cutting and Coagulation and Accessories
Product Code:	GEI
FDA Panel:	General and Plastic Surgery

III. PREDICATE DEVICE

Predicate Devices:	Spetzler™ Malis® Standard Bipolar Forceps, K121426 (primary predicate) Karl Storz Xenon Light Source and Telescope, K962595 (reference device)

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

IV. DEVICE DESCRIPTION

The Spetzler™ Malis® Dual Illuminating Bipolar Forceps are sterile, single-use devices for use in electrosurgery. The forceps are a bayonet style and incorporates a twin pin cord in the proximal end for connection to a bipolar electrosurgical generator via a generic twin pin, female socket receptacle cord set. A fiberoptic cable is bonded to each tine and mates to a proprietary connector at the proximal end. The connector mates with an adaptor that is inserted in the illumination port of an endoscopic ligthsource.

V. INDICATIONS FOR USE

The Spetzler™-Malis® Dual Illuminating Bipolar Forceps are designed for use with the Malis® Bipolar electrosurgical generators. The disposable Spetzler™-Malis® Dual Illuminating Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue and to supply light for surgical procedures.

VI. COMPARISION OF TEHCNOLOGICAL CHARACTERISITICS:

Element	Subject Device **Spetzler™ Malis® Dual Illuminating Bipolar Forceps**	Predicate Device **Spetzler™ Malis® Standard Bipolar Forceps**	Reference Device **Karl Storz Xenon Light source with Telescope**
510(k) Number	K160103	K121426	K962595
Indications for Use	The Spetzler™ Malis® Dual Illuminating Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue l·yŘ ű2 ădzLJLJfè fλ∃Kű ₮2ℕ ădzℕ∃λǑl·f LJℕ2ǑŜŘdzℕŜă.	The Spetzler™ Malis® Standard Bipolar Forceps are single use devices sold sterile and are intended for use in electrosurgery for coagulation of tissue.	This device is designed to supply light for endoscopic diagnostic and surgical procedures.

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

VI. COMPARISION OF TEHCNOLOGICAL CHARACTERISITICS:

Element	Subject Device Spetzler™ Malis® Dual Illuminating Bipolar Forceps	Predicate Device Spetzler™ Malis® Standard Bipolar Forceps	Reference Device Karl Storz Xenon Light source with Telescope
Product Code	GEI	GEI	FFS
Forceps Design	Bayonet Style	Bayonet Style	Not applicable
Patient Contact Material	Silver Plated aluminum base with PVDF insulation	Silver Plated aluminum base with PVDF insulation	Not applicable
Electrical Safety Testing	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	Not Known
Size Offerings Overall Length	8 inches and 9 inches	7 inches, 8 inches and 9 inches	Not applicable
Size Offerings Distal Tip	0.5 mm 1.0 mm 1.5mm	0.5 mm 1.0 mm 1.5mm	Not applicable
Packaging Configuration	Rigid PETG Tray with a Tyvek 1073B Lid	Rigid PETG Tray with a Tyvek 1073B Lid	Not applicable
Method of sterilization	ETO	ETO	Not applicable
Sterility Assurance Level	10^{-6}	10^{-6}	Not applicable

VII. SUMMARY OF NON-CLINICAL TESTS:

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

A series of bench tests were performed to assess the non-stick and illumination features of the forceps. The results are summarized below.

Substantial Equivalence Testing, Primary Function, Non Stick Coagulation		
Parameter	**Subject Device 80-7621**	**Predicate Device 80-1273**
COAG Setting	25 Malis Units	25 Malis Units
Illumination Output	200-204 mW	N/A
Accessory Cord	80-1184 (Single Use)	80-1184 (Single Use)
Non-Stick COAG Events	500+	500+
Results	**Pass/Equivalent**	**Pass/Equivalent**

Comparison of Beef Liver surface temperature rise after 30 minutes of continuous illumination			
Parameter	**Subject Device**	**Reference Device**	**Analysis**
Device Catalog Number	Synergetics Forceps 80-7621	Karl Storz Telescope 27023ABA	Unique
Source Connection Means	Synergetics Adapter 80-7630	Karl Storz Fiber Cable 495NE	Equivalent
Lightsource	Karl Storz 300W Xenon	Karl Storz 300W Xenon	Identical
Adapter/Cable Output [mW]	1230 (non-standard adapter @ 75% setting)	3400 100% output	Equivalent (<Cable)
Device Output [mW] MAX	335-340 (1.5x Typ. Max)	326	Equivalent (<Scope)
Liver Steady State Temperature Rise over Ambient [^{0}F] after 30 min. exposure	4 degrees F	6-8 degrees F	Equivalent ($\leq$110% of Scope & $\leq$ 10 degrees F after 30 minutes)

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Illumination Transmission Levels for Subject Device and Reference Device			
Parameter	**Subject Device**	**Reference Device**	**Analysis**
Device Catalog Number	Synergetics Forceps 80-7621	Karl Storz Telescope 27023ABA	Unique
Source Connection Means	Synergetics Adapter 80-7630	Karl Storz Fiber Cable 495NE	Equivalent
Lightsource	Karl Storz 300W Xenon	Karl Storz 300W Xenon	Identical
Adapter/Cable Output [mW] 100% output	400 (Standard Adapter)	3400	Equivalent (<Cable)
Device Output [mW] MAX, 100% Setting	220	326	Equivalent (<Scopes)
Device Output [mW] AVG, 100% Setting	207	326	Equivalent (<Scopes)

Comparative Light Output Readings from Subject Forceps and Reference Device			
Parameter	**Subject Device**	**Reference Device**	**Analysis**
Device Catalog Number	Synergetics Forceps 80-7621	Karl Storz Telescope 27023ABA	Unique
Source Connection Means	Synergetics Adapter 80-7630	Karl Storz Fiber Cable 495NE	Equivalent
Lightsource	Karl Storz 300W Xenon	Karl Storz 300W Xenon	Identical
Adapter/Cable Output [mW]	400	3400	Equivalent (<Cable)
Device Output [mW] MAX	220	326	Equivalent (<Scope)
Tip Temperature [^{0}F] MAX	186	171	Equivalent (≤110% of Scope)

Synergetics™

Spetzler™ Malis® Dual Illuminating Bipolar Forceps

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

Comparative Light Output Readings from Subject Forceps and Reference Device			
Parameter	**Subject Device**	**Reference Device**	**Analysis**
Device Output [mW] AVG	207 (6pc sample)	326 (1 pc sample)	Equivalent (<Scope)
Tip Temperature [^{0}F] AVG	164.5 (6pc sample)	171 (1pc sample)	Equivalent (≤110% of Scope)

Bench testing, comparative performance testing to the predicate device, and relevant electrical safety testing to IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety, IEC 60601-1-2, Medical Electrical Equipment Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility, and IEC 60601-2-2, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment was performed on the Spetzler™ Malis® Dual Illuminating Bipolar Forceps**.**

The non-clinical testing supports a determination of substantially equivalency to the predicate device.

VIII. SUBSTANTIAL EQUIVALENCE BASIS:

The conclusions performed by independent laboratories and internal comparative bench testing provide objective evidence to substantiate the Spetzler™ Malis® Dual Illuminating Bipolar Forceps is as safe and effective as the predicate device, the Spetzler™ Malis® Standard Bipolar Forceps.