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

December 12, 2016

ShineMed, LLC
Mr. Rogelio Insignares
Operating Manager
7200 Aloma Ave.,
Winter Park, Florida 32792

Re: K160969
Trade/Device Name: ShineMed Reloadable Open Cutting Stapler, ShineMed Curved Intraluminal Cutting Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 15, 2016
Received: November 23, 2016

Dear Mr. Insignares:

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,

David Krause -S

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)*
160969

Device Name

ShineMed Reloadable Open Cutting Stapler

Indications for Use *(Describe)*

ShineMed Reloadable Open Cutting Staplers (ROCS) have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

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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PRAStaff@fda.hhs.gov

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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)*
160969

Device Name

ShineMed Curved Intraluminal Cutting Stapler

Indications for Use *(Describe)*

ShineMed Curved Intraluminal Cutting Staplers (CICS) have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.

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.

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510(k) Summary

A. ASSIGNED 510(k) NUMBER:	K 160969
B. SUBMITTER:	ShineMed LLC 7200 Aloma Ave., Suite A Winter Park, FL 32792 Tel. No: (407) 960-5636
C. CONTACT PERSON:	Mr. Rogelio A. Insignares Operating Manager
D. DATE PREPARED:	December 5, 2016
E. TRADE/PROPRIETARY NAME:	ShineMed Reloadable Open Cutting Stapler ShineMed Curved Intraluminal Cutting Stapler
F. COMMON/USUAL NAME:	Staple, Implantable
G. CLASSIFICATION NAME:	Staple, Implantable
H. REGULATORY CLASS:	II
I. PRODUCT CODE:	GDW, 21 CFR 878.4750
J. PREDICATE DEVICE(S):	Covidien™ Staplers, including: DST Series™ GIA™ Staplers (K111825) Autosuture™ Circular EEA™ Surgical Stapler (K062850)

K. DEVICE DESCRIPTION:

Both ShineMed Reloadable Open Cutting Staplers and predicate DST Series™ GIA™ Staplers place two, double-staggered rows of titanium staples and simultaneously divide the tissues between the two double rows. The size of the staples is determined by the selection of the appropriate single use loading unit that is available in 60mm, 80mm, and 100mm lengths:

- 3.8mm staple size single use loading unit (blue cartridge) (60mm, 80mm, and 100mm lengths)
- 4.8mm staple size single use loading unit (green cartridge) (60mm, 80mm, and 100mm lengths)

Both ShineMed Curved Intraluminal Cutting Staplers and predicate Autosuture™ Circular EEA™ Surgical Staplers place a circular, double staggered row of titanium staples and resect the excess tissue, creating a circular anastomosis. They are indicated for use in the creation of anastomoses in various surgical procedures in both open and laparoscopic surgeries. The stapler is offered in 25mm (white), 28mm (blue), and 31mm (green) diameters and with 4.8mm staple size.

L. INTENDED USE:

ShineMed Reloadable Open Cutting Staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.

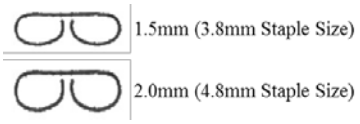
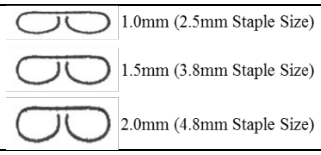
ShineMed Curved Intraluminal Cutting Staplers have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.

M. COMPARISON TO PREDICATE DEVICE:

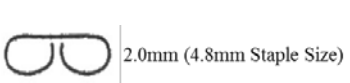
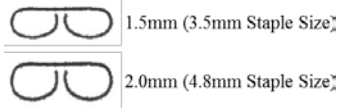
ShineMed Reloadable Open Cutting Staplers and Curved Intraluminal Cutting Staplers are substantially equivalent in their Indications for Use to their predicate devices, respectively.

ShineMed Reloadable Open Cutting Staplers and Curved Intraluminal Cutting Staplers are substantially equivalent in design and performance specifications to their predicate devices. The only design difference is that the ShineMed Staplers are using round titanium wire for staples, rather than flat titanium wire used in the predicate devices. However, this difference will not impact the fundamental scientific technology of the predicate devices with regards to stapling technologies.

The ShineMed Reloadable Open Cutting Stapler has similar features as compared to the predicate device as shown in table below:

Item	ShineMed Reloadable Open Cutting Stapler	DST Series™ GIA™ Staplers (K111825)
Regulatory Information		
Product Code	GDW	GDW
Regulation No.	21 CFR 878.4750	21 CFR 878.4750
Class	II	II
Intended Use		
Intended Use	ShineMed Reloadable Open Cutting Staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.	DST Series™ GIA™ Staplers have applications in abdominal, gynecological, pediatric and thoracic surgical procedures for resection, transection and creation of anastomosis.
Technical Information		
Deployment	Cartridge based deployment (up to 8 firings per stapler) for single patient use.	Cartridge based deployment (up to 8 firings per stapler) for single patient use.
Staple Line Length	60mm, 80mm, and 100mm	60mm, 80mm, and 100mm
Open Staple Height	3.8mm and 4.8 mm	2.5mm, 3.8mm and 4.8mm
Closed Staples Height		
Rows of Staple Line per Side	2	2
Staple Cross Section:		
Material and Biocompatibility Information		
Implantable Material	Unalloyed Titanium conforms to ASTM F67-13.	Unalloyed Titanium
Body material patient short-time contact	Medical Grade Polycarbonate and Stainless Steel	Medical Grade Polycarbonate and Stainless Steel
Biocompatibility	All components of ShineMed Reloadable Open Cutting Staplers are comprised of materials, which are in accordance with relevant parts of ISO Standard 10993.	All components of DST Series™ GIA™ Staplers are comprised of materials, which are in accordance with relevant parts of ISO Standard 10993.
Packaging and Sterilization		
Sterilization Package	PET tray with Tyvek lid	PET tray with Tyvek lid
Sterilization Sterility Assurance Level	Gamma Irradiation SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}
Labeling	Conforms to 21 CFR part 801 and 830	Conforms to 21 CFR part 801 and 830

The ShineMed Curved Intraluminal Cutting Stapler has similar features as compared to the predicate device as shown in table below:

Item	ShineMed Curved Intraluminal Cutting Stapler	Autosuture™ Circular EEA™ Surgical Stapler
Regulatory Information		
Product Code	GDW	GDW
Regulation No.	21 CFR 878.4750	21 CFR 878.4750
Class	II	II
Intended Use		
Intended Use	ShineMed Curved Intraluminal Cutting Staplers have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.	Autosuture™ Circular EEA™ Surgical Staplers have applications throughout the alimentary tract for the creation of end-to-end, end-to-side and side-to-side anastomoses in both open and laparoscopic surgeries, including bariatric surgery.
Technical Information		
Operation Principle	Cut and staple by manually squeezing the handle.	Cut and staple by manually squeezing the handle.
Safety Mechanism	– Safety release underneath the handle for preventing misfiring. – Indicator window for preventing inappropriate use on tissues.	– Safety release underneath the handle for preventing misfiring. – Indicator window for preventing inappropriate use on tissues.
Shell Outside Diameter	25.6mm, 28.6mm, 31.6 mm	21mm, 25mm, 28mm, 31mm, 33mm
Outside Knife Diameter	16.6mm, 19.6mm, 22.6mm	12.5mm, 16.6mm, 19.5mm, 22.5mm, 24.6mm
Number of Staples	22, 26, 30	18, 22, 26, 30, 32
Open Staple Height	4.8 mm	3.5mm, 4.8mm
Closed Staples Height		
Rows of Staple Line per Side	2	2
Staple Cross Section:		
Material and Biocompatibility Information		
Implantable Material	Unalloyed Titanium conforms to ASTM F67-13.	Unalloyed Titanium
Body material patient short-time contact	Medical Grade Polycarbonate and Stainless Steel	Medical Grade Polycarbonate and Stainless Steel

Item	ShineMed Curved Intraluminal Cutting Stapler	Autosuture™ Circular EEA™ Surgical Stapler
Biocompatibility	All components of ShineMed Curved Intraluminal Cutting Staplers are comprised of materials, which are in accordance with relevant parts of ISO Standard 10993.	All components of Autosuture™ Circular EEA™ Surgical Staplers are comprised of materials, which are in accordance with relevant parts of ISO Standard 10993.
Packaging and Sterilization		
Sterilization Package	PET tray with Tyvek lid	PET tray with Tyvek lid
Sterilization Sterility Assurance Level	Gamma Irradiation SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}
Labeling	Conforms to 21 CFR part 801 and 830	Conforms to 21 CFR part 801 and 830

N. IMPLANTABLE MATERIALS: ShineMed Reloadable Open Cutting Staplers and Curved Intraluminal Cutting Staplers are using unalloyed titanium that conforms to ASTM F67-13. The predicate devices are also using the unalloyed titanium.

O. PATIENT SHORT-TIME CONTACT MATERIALS: ShineMed Reloadable Open Cutting Staplers and Curved Intraluminal Cutting Staplers are using Medical Grade Polycarbonate and Stainless Steel as patient direct contact material. The predicate devices are using the same material.

P. BIO-COMPATIBILITY: All components of ShineMed Reloadable Open Cutting Staplers and Curved Intraluminal Cutting Staplers and the predicate devices are comprised of materials that are in accordance with relevant parts of ISO Standard 10993.

Biocompatibility Testing

The staplers are considered tissue contacting for a duration less than 24 hours, while the staples are considered permanent implants. The titanium material of implantable staples conforms to ASTM F67-13.

The biocompatibility evaluations of ShineMed Reloadable Open Cutting Stapler and Curved Intraluminal Cutting stapler were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process”, as recognized by FDA. The staplers of testing include the following tests:

- Cytotoxicity (ISO 10993-5:2009 "Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity")
- Sensitization (ISO 10993-10: 2010 "Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization")
- Irritation (ISO 10993-10: 2010 "Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization")
- Acute Systemic Toxicity (ISO 10993-11: 2006 "Biological Evaluation of Medical Devices -- Part 11: Tests for Systemic Toxicity")
- ISO 10993-11:2006 Pyrogen Test.
- USP 38-NF33:2015, <85> Bacterial Endotoxins Test.

The devices are biocompatible and meet pyrogen specification limits.

Q. TESTING DATA:

Performance Bench Testing

Non-clinical bench tests were conducted to evaluate the function, performance, safety, reliability of ShineMed products and the equivalence to the predicate devices. Results are summarized as follows:

For ShineMed Reloadable Open Cutting Stapler,

1. Functionality Testing:
   - Functionality testing was completed to confirm device features were functioning as intended and identical to the predicate device.
   - Safety lockout in the cartridge was deployed successfully after fired to prevent reloading a fired cartridge. This safety feature is identical to the predicate device.
   - Locking lever handle was able to ensure proper tissue compression through securing distance between cartridge and anvil. This design is identical to the predicate device.
   - Shipping wedge was provided to prevent misfiring during shipment. The design of the shipping wedge is identical to the predicate device.
2. Performance Comparison Testing:
   - Integrity of the stapler line was confirmed via visual inspection of the stapling, which was equivalent to the predicate devices.

- Performance of anastomosis was evaluated through anastomosis leak test and bursting test of the staple line. Comparison was performed to confirm that the performance of ShineMed products are substantially equivalent to the predicate devices.
- Dimensional tests were conducted to confirm that the staple formation heights of ShineMed products after firing are statistically identical to those of the predicate devices.

3. Reliability Testing
   - Reliability testing was performed to confirm that the ShineMed Reloadable Open Cutting Stapler can fire 8 times with consistent functionality and performance.
4. Package Testing
   - Integrity of the primary package of ShineMed products was confirmed through Visual Inspection and Dye Penetration Testing.
   - Package seal strength testing was conducted to confirm that the seal strength of the primary packages of ShineMed products meet design requirements and are not compromised through sterilization and current shipping and handling methods.
5. Shelf-Life Testing
   - Shelf-life testing was completed and passed in accordance with ASTM F1980.

For ShineMed Curved Intraluminal Cutting Stapler,

1. Functionality Testing:
   - Functionality testing was completed to confirm device features were functioning as intended and identical to the predicate device.
   - Safety mechanism was deployed successfully to prevent improper use. The safety release can prevent firing the device when the thickness of tissue between the cartridge and the anvil is not compressed to specified range. This safety feature is identical to the predicate device.
2. Performance Comparison Testing:
   - Integrity of the stapler line was confirmed via visual inspection of the stapling, which was equivalent to the predicate devices.
   - Performance of anastomosis was evaluated through anastomosis leak test and bursting test of the staple line.

Comparison was performed to confirm that the performance of ShineMed products are substantially equivalent to the predicate devices.

- Dimensional tests were conducted to confirm that the staple formation heights of ShineMed products after firing are statistically identical to those of the predicate devices.

4. Package Testing
   - Integrity of the primary package of ShineMed products was confirmed through Visual Inspection and Dye Penetration Testing.
   - Package seal strength testing was conducted to confirm that the seal strength of the primary packages of ShineMed products meet design requirements and are not compromised through sterilization and current shipping and handling methods.
5. Shelf-Life Testing
   - Shelf-life testing was completed and passed in accordance with ASTM F1980.

Clinical Evaluation

Clinical evaluation is not applicable. Clinical Data is not required to support this submission.

R. CONCLUSION: ShineMed Reloadable Open Cutting Stapler and Curved Intraluminal Cutting Stapler are compared to legally marketed devices with respect to intended use and technological characteristics. In addition, non-clinical bench testing is completed to validate the performance of the device and ensure the ShineMed Reloadable Open Cutting Stapler and Curved Intraluminal Cutting Stapler function as intended. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate devices for its intended use.