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, 2014

Touchstone International Medical Science Company, Ltd.
Mr. Jo Qiao
Management Representative
21A Science Plaza, International Science Park
No. 1355 Jinjihu Avenue
Suzhou, 215021 P.R. CHINA

Re: K141097
Trade/Device Name: CSC Series Intraluminal Stapler for Single Use, PPHplus Series PPH Stapler, and TST Series Tissue-Selecting Therapy Stapler
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: August 26, 2014
Received: August 29, 2014

Dear Mr. Qiao:

This letter corrects our substantially equivalent letter of September 26, 2014.

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]), 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,

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)*

Device Name
CSC Series Intraluminal Stapler for Single Use

Indications for Use *(Describe)*
The CSC Series Intraluminal Stapler for Single Use 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
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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)*

Device Name
PPHplus Series PPH Stapler and Purse Sets for Single Use

Indications for Use *(Describe)*
The PPHplus Series PPH Stapler and Purse Sets for Single Use have application for general surgical treatment of hemorrhoids.

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)

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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)*

Device Name
TST Series Tissue-Selecting Therapy Stapler

Indications for Use *(Describe)*
The TST Series Tissue-Selecting Therapy Stapler have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.

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)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Submission Date: 04/18/2014

2. Sponsor Identification

Touchstone International Medical Science Co., Ltd.
21A Science Plaza, International Science Park,
No.1355 Jinjihu Avenue,
Suzhou, 215021 P.R.CHINA

Establishment Registration Number:

Contact Person: Jo.Qiao
Position: Management Representative
Tel: +86 512 62991985
Fax: +86 512 62991998
Email: tsmo@touchstone.hk

3. Proposed Device Identification

3.1 Proposed Device for CSC Series

3.1.1 Proposed Device Name: CSC Series Intraluminal Stapler for Single Use

3.1.2 Proposed Device Common Name: Stapler

3.1.3 Regulatory Information

Classification Name: staple, implantable
Classification: II
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Review Panel: General & Plastic Surgery

3.1.4 Intended Use Statement

The CSC Series Intraluminal Stapler for Single Use 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.

3.1.5 Device Description

The proposed device, CSC Series Intraluminal Stapler for Single Use is a sterilized and disposable surgical instrument intended to be used 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.

It places a double staggered, circular row of titanium staples upon activation, which was achieved by squeezing the handles firmly as far as they could go. Immediately after formation of the staples, the excess tissue will be resected by the circular knife, and then a circular anastomosis is created.

3.2 Proposed Device for PPHplus Series

3.2.1 Proposed Device Name: PPHplus Series PPH Stapler and Purse Sets for Single Use

3.2.2 Proposed Device Common Name: Stapler

3.2.3 Regulatory Information

Classification Name: staple, implantable
Classification: II
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Review Panel: General & Plastic Surgery

3.2.4 Intended Use Statement

The PPHplus Series PPH Stapler and Purse Sets for Single Use have application for general surgical treatment of hemorrhoids.

3.2.5 Device Description

The proposed device, PPHplus Series PPH Stapler and Purse Sets for Single Use is a sterilized and disposable surgical instrument, which has application for general surgical treatment of hemorrhoids.

It is a set of instruments that place a double staggered, circular row of titanium staples. Immediately after the formation of staples, the circular knife blade resects the excess of compressed mucosa. The sets are commonly used in the procedures for prolapsed and hemorrhoids. They are also used for other applications when circular or semicircular stapling of anorectic tissue is required.

3.3 Proposed Device for TST Series

3.3.1 Proposed Device Name: TST Series Tissue-Selecting Therapy Stapler

3.3.2 Proposed Device Common Name: Stapler

3.3.3 Regulatory Information

Classification Name: staple, implantable
Classification: II
Product Code: GDW
Regulation Number: 21 CFR 878.4750
Review Panel: General & Plastic Surgery

3.3.4 Intended Use Statement

The TST Series Tissue-Selecting Therapy Stapler have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.

3.3.5 Device Description

The proposed device,TST Series Tissue-Selecting Therapy Stapler is a sterilized and disposable surgical instrument, to be used in the surgical treatment of prolapse and hemorrhoids. This device also uses the Stapled Transanal Rectal Resection (STARR) surgical treatment of anorectal wall defects and obstructed defecation syndrome, with a single-fire staple.

It is a set of instruments that facilitate delivery of a circumferential, staggered, double-row of staples while simultaneously resecting a segment of compressed soft tissue. The set is also Used for other applications where circular or semicircular or 1/3 circular stapling of anorectal tissue is desired.

4. Predicate Device Identification

4.1 Predicate Device for Disposable Circular Stapler

510(k) Number: K131511

Product Name: Disposable Circular Stapler

Manufacturer: Changzhou Sinolinks Medical Innovation Co., Ltd.

4.2 Predicate Device for Disposable Hemorrhoidal Stapler

510(k) Number: K131511

Product Name: Disposable Hemorrhoidal Stapler

Manufacturer: Changzhou Sinolinks Medical Innovation Co., Ltd.

4.3 Predicate Device for PROXIMATE® HCS

510(k) Number: K030925

Product Name: PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories(PPH01)

Manufacturer: Ethicon Endo-Surgery, Inc.

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. These tests include:

Performance Testing, including Physical Specification, Closed Staple Height Dimensions, Pressure Resistance Evaluation, Maximum Tensile Strength of Staple Line Repair and Force Required to Fire Stapler.

Endotoxin Limit

Package Integrity, including dye penetration tests and seal strength test.

Shelf Life

6. Substantially Equivalent (SE) Conclusion

The following table compares the device to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 CSC Series Intraluminal Stapler for Single Use

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The CSC Series Intraluminal Stapler for Single Use 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.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Indicator for appropriate range of desired closed staple height.	Same
	Safety Release for preventing from mis-firing	Same
Outsider Diameter	21, 25, 29, 33 mm	Similar
Cutting Diameter	12.7, 16.4, 20.0, 24.4, mm	Similar
Number of Staples	16, 20, 24, 28	Similar
Closed Staple Height	2.0 mm	Similar
Closed Staple Form		Same
Hardness (Circular knife)	$\geqq 380HV_{0.2}$	Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Same
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Outsider Diameter, Cutting Diameter, Number of Staples, Closed Staple Height. Between the proposed and the predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, CSC Series Intraluminal Stapler for Single Use, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Circular Stapler (K131511), in respect of safety and effectiveness.

Table 3-2 PPHplus Series PPH Stapler and Purse Sets for Single Use

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The PPHplus Series PPH Stapler and Purse Sets for Single Use have application for general surgical treatment of hemorrhoids.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Indicator for appropriate range of desired closed staple height.	Same
	Safety Release for preventing from mis-firing	Same
Outsider Diameter	33.5 mm	Similar
Cutting Diameter	24.4 mm	Similar
Number of Staples	32	Same
Closed Staple Height	1.3, 1.6 mm	Similar
Closed Staple Form		Same
Hardness (Circular knife)	$\geqq 380HV_{0.2}$	Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Same
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Outsider Diameter, Cutting Diameter, Closed Staples Height. Between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, PPHplus Series PPH Stapler and Purse Sets for Single Use, is determined to be Substantially Equivalent (SE) to the predicate device, Disposable Hemorrhoidal Stapler(K131511), in respect of safety and effectiveness.

Table 3-3 TST Series Tissue-Selecting Therapy Stapler

Item	Proposed Device	Predicate Device
Product Code	GDW	Same
Regulation No.	21 CFR 878.4750	Same
Class	II	Same
Intended Use	The TST Series Tissue-Selecting Therapy Stapler have application for general surgical treatment of anorectal wall defects by means of transanal stapling and resection of mucosal and musculomucosal tissue.	Same
Operation Principle	Manual	Same
Cutting Mechanism	Circular Knife	Same
Safety Mechanism	Indicator for appropriate range of desired closed staple height.	Same
	Safety Release for preventing from mis-firing	Same
Outsider Diameter	31.5, 33.5, 36.5 mm	Similar
Cutting Diameter	22.4, 24.4, 26.4 mm	Similar
Number of Staple	30, 32, 34	Similar
Closed Staple Height	1.3, 1.6, 2.0 mm	Similar
Closed Staple Form		Same
Hardness (Circular knife)	$\geqq 380HV_{0.2}$	Same
Pressure Resistance after Suturing	≥3.6kPa	Same
Staple Materiel	Unalloyed Titanium conforms to ASTM F 67-06	Same
Stapler Materials	Stainless Steel, Polycarbonate	Same
Sterilization	Irradiation Sterilized, SAL: 10^{-6}	Same
Endotoxin Limit	20 EU per Product	Same
Package	Tray with Tyvek Paper	Same
Labeling	Conforms to 21 CFR part 801	Same

Difference in Outsider Diameter, Cutting Diameter, Number of Staple, Closed Staple Height. Between the proposed and predicate device are discussed in the 510(k) submission documents, it is concluded that these differences will not affect the effectiveness and safety of the proposed device.

The proposed device, TST Series Tissue-Selecting Therapy Stapler, is determined to be Substantially Equivalent (SE) to the predicate device, PROXIMATE® HCS Hemorrhoidal Circular Stapler and Accessories(K030925), in respect of safety and effectiveness.