November 14, 2022

Beijing ZKSK Technology Co.,Ltd
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
CHINA

Re: K213217
Trade/Device Name: Disposable hemoclip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: October 9, 2022
Received: October 11, 2022

Dear Boyle Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
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Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213217

Device Name
Disposable Hemoclip

Indications for Use *(Describe)*
Disposable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

1) Endoscopic marking, 2)
Hemostasis for:
Mucosal/sub-mucosal defects <3cm,
Bleeding ulcers,
Arteries < 2mm,
Polyps < 1.5cm in diameter,
Diverticula in the colon,

3) As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.

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.

510(k) Summary

K213217

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

Company name: Beijing ZKSK Technology Co., Ltd.

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Date of Preparation: Oct.09, 2022

Designated Submission Correspondent

Mr. Boyle Wang

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2.0 Device information

Trade name: Disposable Hemoclip

Common name: Hemorrhoidal ligator

Classification name: Hemorrhoidal ligator

Model(s):

HC-10-165/26P, HC-10-195/26P, HC-10-230/26P, HC-11-165/26P, HC-11-195/26P, HC-11-230/26P, HC-14-165/26P, HC-14-195/26P, HC-14-230/26P, HC-16-165/26P, HC-16-195/26P, HC-16-230/26P ,HC-10-165/26, HC-10-195/26, HC-10-230/26, HC-11-165/26, HC-11-195/26, HC-11-230/26, HC-14-165/26, HC-14-195/26, HC-14-230/26, HC-16-165/26, HC-16-195/26, HC-16-230/26 .

Model difference：There are 30 models of Disposable Hemoclip. The main structure and material of each specification model are completely consistent. The outer tube of the plastic wrap type has one more layer of plastic than that of the ordinary type.

3.0 Classification

Production code: PKL

Regulation number: 21CFR 876.4400

Classification: Class II

Panel: Gastroenterology/Urology

4.0 Predicate device information

Manufacturer: Anrei Medical (Hangzhou) Co., Ltd

Device: Single Use Rotatable and Repositionable Hemoclip
510(k) number: K201771

5.0 Intended Use/Indication for Use Statement

Disposable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of:

1）Endoscopic marking,

2）Hemostasis for:

Mucosal/sub-mucosal defects <3cm,

Bleeding ulcers,

Arteries < 2mm,

Polyps < 1.5cm in diameter,

Diverticula in the colon,

3）As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.

6.0 Device description

The clip is pre-installed at the front of the chuck releaser, the chuck releaser is delivered by the conveyor duct through the endoscope to the Gastrointestinal (GI) tract system finds the bleeding site, thumb ring releases the chuck, so that the clip clamps the bleeding site to stop the bleeding.

The proposed device is a sterile, single-use endoscopic clipping device. It is consisted of two main components: the delivery system and the HC series. The delivery system is available in three different working length. The clip is deployed from the delivery system during use. The hemoclip jaws can be opened and closed no more than five times prior to deployment, aiding in repositioning of the clip at the lesion site.

There are 30 models of Disposable Hemoclip.The main structure and material of each specification model are completely consistent. The outer tube of the plastic wrap type has one more layer of plastic than that of the ordinary type.The material is PE, but the other is the same.

7.0 Technological Characteristic Comparison Table

Table 3 - General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	PKL	PKL	Identical
Regulation No.	21 CFR 878.4400	21 CFR 878.4400	Identical
Class	II	II	Identical
Product name	Disposable Hemoclip	Single Use Rotatable and Repositionable Hemoclip	Similar
510(k) No.	K213217	K201771	Different
Models	HC-10-165/26P, HC-10-195/26P, HC-10-230/26P, HC-11-165/26P, HC-11-195/26P, HC-11-230/26P, HC-14-165/26P, HC-14-195/26P, HC-14-230/26P, HC-16-165/26P, HC-16-195/26P, HC-16-230/26P ,HC-10-165/26, HC-10-195/26, HC-10-230/26, HC-11-165/26, HC-11-195/26, HC-11-230/26, HC-14-165/26, HC-14-195/26, HC-14-230/26, HC-16-165/26, HC-16-195/26, HC-16-230/26	Not publicly available	Different
Intended Use/Indications for Use	Disposable hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of: 1）Endoscopic marking, 2）Hemostasis for: Mucosal/sub-mucosal defects <3cm, Bleeding ulcers, Arteries < 2mm, Polyps < 1.5cm in diameter, Diverticula in the colon, 3）As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively.	Single Use Rotatable and Repositionable Hemoclip is indicated for clip placement within the Gastrointestinal (GI) tract for the purpose of: 1）Endoscopic marking 2）Hemostasis for: Mucosal/sub-mucosal defects < 3cm, Bleeding ulcers, Arteries < 2mm, Polyps < 1.5cm in diameter, Diverticula in the colon, 3）As a supplementary method, closure of GI tract luminal perforations < 20mm that can be treated conservatively	Identical
Configuration	Delivery system and HC series	Delivery system and jaw	* Gap 1
Material	SUS304	SUS304	Identical
Sterility	Sterile	sterile	Identical
Sterilization method	EO	EO	Identical
Shelf life	3 years	3 years	Identical
Single Use	Yes	Yes	Identical
Rotation function	rotatable	rotatable	Identical
Open width	8mm, 10mm, 12mm， 14mm and 16mm	9mm, 11mm, 13mm and 16mm	* Gap 2
Working length	1650mm, 1950mm, 2300mm	1650mm, 1950mm, 2300mm and 2700mm	* Gap 3

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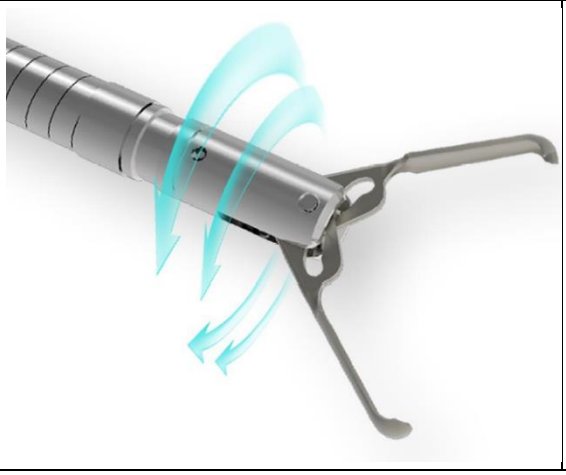
Minimal working channel	2.8mm	2.8mm	Identical
Release the performance	The clip of the tissue clamp shall be able to open and close smoothly, and the slider shall be pushed and pulled to successfully complete the clamping action. After the clip assembly is disengaged from the device, the remaining part can be manually removed from the analog endoscope tube. The force to remove the clip from the endoscope tube is not more than 5N.	Not publicly available	* Gap 6
Clamping force	After the tissue clamp is used to clamp the isolated pig stomach tissue, 100g weight is applied to the clamp seat, and it shall not be separated for 1min.	Not publicly available	* Gap 7
Get out of the strength	greater than 20N	Not publicly available	* Gap 8
Relocatable	The clamp shall be able to open normally and separate from the tissue. It shall be able to withstand repeated operation for 5 times.	Not publicly available	* Gap 9
Clip assembly mechanical integrity	Visually observe that the clip assembly should fall off as a whole, and the connecting parts between clip assemblies should not fall off or become loose.	Not publicly available	*Gap 10
Clamping release force	The force separating the clamp assembly from the outer tube after biting and locking shall be greater than 20N.	Not publicly available	*Gap 11
Open and close of hemoclip	Push the slider towards the far end, and the clip should be able to open. Pull the slider towards the near end, and the clip shall be closed. This method should be able to withstand repeated operation for 5 times	Not publicly available	* Gap12
In vitro Cytotoxicity	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity	Identical
Intradermal reactivity	Under the condition of the test, no potential intracutaneous reactions	/	* Gap4
Skin Sensitization	Under the condition of the test, no potential sensitization	Under the condition of the test, no potential sensitization	Identical
Irritation	/	No irritation	* Gap 5

Acute Systemic Toxicity	No acute toxicity	No acute toxicity	Identical
Material-mediated Pyrogens	No pyrogen	No pyrogen	Identical
Sub-acute Systemic Toxicity	No sub-acute toxicity	No sub-acute toxicity	Identical

* Gap analysis:

Gap 1: The configuration of the proposed device is Delivery system and HC series，the configuration of the predicate device is Delivery system and jaw, this is just a different description of the text, from the following structural diagram can be seen that HC series is jaw, this difference does not create additional risks to the device.

Item	**Proposed device**	**Predicated device**
Configuration		

Gap 2-3： the two devices have some little deviation in product performance, but the difference in the performance test result does not raise additional questions for safety and effectiveness.

Gap 4-5, the two devices have some little deviation in the irritation ,this difference does not create additional biocompatibility risks to the device.

* Gap 6-11；performance test was performed on both the proposed device and predicate device and the test result demonstrated that there was no signification difference between them.

8.0 Non-Clinical Test Conclusion

The proposed device was tested and conformed to the related recognized standards

2-258 ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing

2-245 ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity.

2-174 ISO 10993-10 Third Edition 2010-08-01, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

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ISO 10993-11:2017 Biological evaluation of medical devices -- Part 11:Tests for systemic toxicity

ISO 10993-7:2008 Biological evaluation of medical devices -- Part 7: Ethylene Oxide Sterilization Residuals.

USP31-NF26 <71> sterility test

ASTM F 1980-16 Standard guidelines for accelerated aging of sterile barrier systems for medical devices

ASTM Fl 886/Fl886M-2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

ASTM F1929-15 Standard test method for detecting seal leaks in porous medical packaging by dye penetration.

ASTM F88/F88M-15 standard method for seal strength of flexible barrier materials

ASTM D3078-02(2013) Standard Test Method for Determination of Flexible Packaging Leakage by Bubble Generation

DIN 58953-6:2016 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized

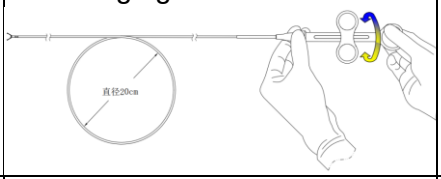
ASTM D4169-16 Standard practice for performance testing of shipping containers and systems(DC-13,Level Ⅱ)

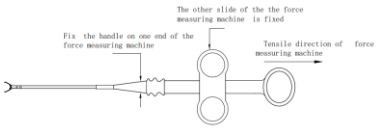
Dimension test was performed on the proposed device and the test result demonstrated that the device could meet its design specification requirement.

Performance test was performed on the proposed device and predicate device and the test result demonstrated that there was no significant difference between them, the test include following items

Items	Test Methodology	Acceptance Criteria	Results
Release the performance	Prepare a piece of 10cm*10cm isolated pig stomach tissue, insert the tissue clamp into the simulated clamp channel with a diameter ≥ 2.8mm, after the clamp assembly extends out of the clamp channel, align the clamp with the tissue, move the slider to the proximal end, until there is resistance on the handle, gradually close the tissue clamp, and then clamp the tissue and lift it away from the desktop. (Note: after feeling resistance, do not continue to move the slider to the near end. If you hear a click, the clip will not reopen).	The clip of the tissue clamp shall be able to open and close smoothly, and the slider shall be pushed and pulled to successfully complete the clamping action. After the clip assembly is disengaged from the device, the remaining part can be manually removed from the analog endoscope tube. The force to remove the clip from the endoscope tube is not more than 5N.	Meet the requirements

	Continue to move the slider towards the near end until the second resistance is reached, where a second click is felt or heard. Continue to move the slider towards the proximal end until the thumb ring is reached. After the clip assembly is released and disengaged, use the manual tension machine to hook the proximal finger ring of the handle, and pull the outer tube of the tissue clip and the adapter out of the simulated clamp channel.		
Clamping force	Fix the ex-vivo pig stomach tissue on a vise or other device and keep it still. Push the slide block of the conveying device to make the clip tissue clamp the tissue, and pull the slide block towards the near end until the clip is closed and the clip assembly is disengaged. Thread the silk thread through the small hole at the rear end of the clamp base, hang a 100g weight on the silk thread, and rotate the soft tissue clamp assembly to open and close repeatedly after 1min. The soft tissue clamp assembly shall not be separated from the tissue.	After the tissue clamp is used to clamp the isolated pig stomach tissue, 100g weight is applied to the clamp seat, and it shall not be separated for 1min.	Meet the requirements
Get out of the strength	The isolated porcine gastric tissue was fixed on the lower side fixture of the electronic universal testing machine and kept moveable. The slider of the delivery device was pushed so that the clip clamped the porcine gastric tissue, and the slider was pulled hard proximally until the clip closed. The position of the slider was kept constant and the clip was always in a closed state. The side of the outer catheter of the tissue clip near the clip assembly was fixed on the upper fixture of the electronic universal testing machine, and the electronic	The force required to remove a deployed clip from the tissue model should be between 0.9N and 2.5N.	Meet the requirements

	universal testing machine was started to measure.		
Surface roughness	Use sample block comparison to compare with the measured surface according to the visual and tactile senses, and judge that the measured surface roughness is equivalent to that value.	The surface roughness parameter Ra of clamps shall not be greater than 0.5μm	Meet the requirements
Hardness	Carry out the Vickers hardness test, the indenter is in contact with the surface of the sample, and the test force is applied perpendicular to the test surface. The test force holding time is 10-15s	The hardness of the clip shall be ≥260HV0.2.	Meet the requirements
Corrosion resistance	The test piece is immersed (the immersion height should not be less than 30mm) and boil for at least 30 minutes in a glass beaker filled with boiling water (4.1); cool it in the test water for at least 1 hour, then take the test piece out of the test water, expose it to the air for 2 hours, and then dry it. Wipe the surface of the test piece vigorously with the cloth	Corrosion resistance of metal caps and clamps shall not be lower than class b requirements of class b of boiling water test method.	Meet the requirements
Rotation performance	Bend the outer tube for a circle with a diameter of 20cm, hold the positioning cap, and then rotate the handle. Visually observe that the clip assembly should rotate smoothly without jamming. As shown in the following figure: 	Visually observe that the clip assembly should follow the handle to rotate 360 ° left and right, and the rotation should be smooth without jamming.	Meet the requirements
Repositionability	Prepare a 10cm*10cm piece of isolated pig stomach tissue, align the clip with the tissue, move the slider to the proximal end, until you feel resistance on the handle, and gradually close the tissue clip, then clamp the tissue and lift it away from the desktop. (Note: after feeling resistance, do not continue to move the slider to the near end. If you hear a click, the clip cannot be reopened.) after the operation	The clamp shall be able to open normally and separate from the tissue. It shall be able to withstand repeated operation for 5 times.	Meet the requirements

	is completed, move the slider to the far end and repeat the above operation for 4 times.		
Hemoclip assembly mechanical integrity	Prepare a piece of 10cm*10cm isolated pig stomach tissue, insert the tissue clamp into the simulated clamp channel with a diameter ≥ 2.8mm. After the clamp assembly extends out of the clamp channel, align the clamp with the tissue, move the slider to the proximal end, until there is resistance on the handle, and gradually close the tissue clamp, clamp the tissue and lift it away from the table. (Note: after feeling resistance, do not continue to move the slider to the near end. If you hear a click, the clip will not reopen). Continue to move the slider towards the near end until the second resistance is felt or heard here. Continue to move the slider toward the near end until you reach the thumb ring.	Visually observe that the clip assembly should fall off as a whole, and the connecting parts between clip assemblies should not fall off or become loose.	Meet the requirements
Clamping release force	As shown in the figure below, fix the handle on one end of the force measuring machine, fix the sliding block on the other end of the force measuring machine, start the force measuring machine in the direction shown in the figure below, and the stretching speed is 200mm/min. As a result, the force separating the clamp assembly from the outer tube after biting and locking shall be greater than 20N  	The force separating the clamp assembly from the outer tube after biting and locking shall be greater than 20N.	Meet the requirements
Open and Close of hemoclip	Gently push the slider toward the far end to open the clip. Pull the slider towards the near end to close the clip.	Push the slider towards the far end, and the clip should be able to open. Pull the slider towards the near end, and the clip shall be closed. This method should be able to withstand repeated operation for 5 times.	Meet the requirements

Reducing substances	Preparation of test solution Take the sample, press 0.2g sample Add 1ml of water and extract for 72 hours at 37°C±1°C. Separate the sample from the liquid, cool to room temperature, and use it as the test solution. Take the same volume of water and place it in a glass container, and prepare a blank control solution in the same way Take 10mL of calibrated potassium permanganate solution and sodium thiosulfate solution and dilute to 0.002 mol/L. Add 10 mL of the test solution to a 250 mL iodine flask, add 1 mL of dilute sulfuric acid and 10 mL of 0.002 mol/L potassium permanganate standard solution, boil for 3 minutes, cool rapidly, add 0.1 g of potassium iodide, close it, and shake well. Immediately titrate with the same concentration of sodium thiosulfate standard solution to light yellow, add 0.25 mL of starch indicator solution, and continue to titrate with sodium thiosulfate standard solution until it is colorless. Titrate the blank control solution in the same way.	The difference in consumption of 0.002mol/L potassium permanganate solution should be less than 2.0mL as compared to the same batch of blank control liquid at the same volume.	0.9ml
Extractable metal content	Accurately measure 25mL of the test solution in a 25mL Nessler colorimetric tube, take another 25mL Nessler colorimetric tube, add 25mL lead standard solution, and add acetate buffer (pH3 .5) 2mL, then add 2mL of thioacetamide test solution, shake well, place for 2min, observe from above on a white background, compare the color depth. If the test solution develops color, a small amount of dilute caramel solution or other non-interfering colored solution can be added to the standard control solution to make it	The total extractable metal content in the test solution shall not exceed 5 g/mL, and the cadmium content shall be less than 0.1 g/mL	Meet the requirements

	consistent with the color of the test solution. Then add 2 mL of thioacetamide test solution to the test solution and the standard control solution, shake well, and place for 2 minutes. Observe from above on a white background to compare the shades of color.		
PH	Take the test solution and the blank control solution, and measure the pH value with an acidity meter. The difference between the two is the test result.	The PH difference between the test solution and the same batch of blank solution shall not exceed 1.0	0.7
Evaporation residue	The evaporating dish is pre-dried to constant weight at 105°C. Measure 50 mL of the test solution into an evaporating dish, evaporate to dryness on a water bath, and dry to constant weight in a constant temperature oven at 105°C. Determine the blank control solution in the same way.	The total amount of dry residue should not exceed 5mg	0.56mg
Ultraviolet absorbance	Take the test solution, use a 1cm cuvette with the blank control solution as a reference within 5h, and measure the absorbance within the specified wavelength range.	Within the wavelength range of 250nm to 320nm, the absorbance of the test solution shall not be greater than 0.1.	0.046
SAL	USP31-NF26 <71> sterility tes	≤10-6	Aseptic growth
EO residue	ISO 10993-7:2008	≤10μg/g	3.72 μg/g
Shelf life	ASTM F 1980-16	3 years	Meet the requirements
In vitro Cytotoxicity	ISO 10993-5 Third edition 2009-06-01	Under the condition of the test, no potential cytotoxicity	Under the condition of the test, no potential cytotoxicity
Intradermal reactivity	ISO 10993-10 Third Edition 2010-08-01,	Under the condition of the test, no potential intracutaneous reactions	Under the condition of the test, no potential intracutaneous reactions
Skin Sensitization	ISO 10993-10 Third Edition 2010-08-01,	Under the condition of the test, no potential sensitization	Under the condition of the test, no potential sensitization
Acute Systemic	ISO 10993-11:2017	Under the condition of the	Under the

Toxicity		test, no acute toxicity	condition of the test, no acute toxicity
Material-mediated Pyrogens	ISO 10993-11:2017	Under the condition of the test, no pyrogen	Under the condition of the test, no pyrogen
Sub-acute Systemic Toxicity	ISO 10993-11:2017	Under the condition of the test, no sub-acute toxicity	Under the condition of the test, no sub-acute toxicity

9.0 Clinical Test Conclusion

No clinical study implemented for the Disposable Hemoclip.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device , the Disposable Hemoclip is as safe, as effective, and performs as well as or better than the legally marketed predicate device K201771.