December 22, 2023

Well Care (Wuhan) Medical Technology Co., Ltd
Zhou Huimin
Quality Manager
No. 11# The No.1 Road Fozuling of East Lake High-Tech
Development Zone
Wuhan, Hubei 430205
China

Re: K230439
Trade/Device Name: WellCare Anoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FER
Dated: November 21, 2023
Received: November 21, 2023

Dear Zhou Huimin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, General Hospital, and Urology Devices
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)*
K230439

Device Name
WellCare Anoscope

Indications for Use *(Describe)*
WellCare Anoscope is intended for transanal use to provide physicians access to the anal sphincter, anus, and rectum and to perform various diagnostic and therapeutic procedures using additional accessories.

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.

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Section 3 510(k) Summary

I 510(k) Submitter

Device Submitter: Well care (Wuhan) medical technology Co., Ltd..
No. 11# The No.1 road
Fozuling of East Lake High-Tech Development Zone Wuhan, Hubei

Contact Person: ZhouHuimin
Quality Manager
Phone: +86-15626465068
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II Device

Trade Name of Device:	WellCare Anoscope
Regulation Number:	21 CFR 876.1500
Classification Name:	Endoscope and acccessories
Product Code:	FER
Regulation Number:	21 CFR 876.1500
Regulatory Class	II
Review Panel	GU - Gastroenterology-Urology

III Predicate Devices

510k Number	K121135
Trade Name of Device:	Family of disposable,sterile and not sterile THD Anoscope,Proctoscope , Rectoscope and Light-scope
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and accessories
Regulatory Class	II
Product Code:	FER

IV Device Description

WellCare Anoscope are intended for the examination of the anus，it also can be used as an auxiliary instrument for hemorrhoid surgery.WellCare Anoscope is composed of Anoscope, Introducer and Sleeve.The anoscopes are divided into the following models according to the way the components are configured and the differences in size：WellCare-ANO-Light Sterile 、 WellCare-ANO-Truncated Sterile.This is a single use, disposable device(s), provided sterile.

V Indications for use

WellCare Anoscope is intended for transanal use to provide physicians access to the anal sphincter, anus, and rectum and to perform various diagnostic and therapeutic procedures using additional accessories.

VI Technological Characteristics Comparison

VI-1: Comparison of WellCare Anoscope

<table>
<tr><th>Device Characteristic</th><th>Subject Device</th><th>Predicate Device (K121135)</th><th>Discussion</th></tr>
<tr><td>Indications for Use</td><td>WellCare Anoscope is intended for transanal use to provide physicians access to the anal sphincter, anus, and rectum and to perform various diagnostic and therapeutic procedures using additional accessories.</td><td>Family of disposable, sterile and not sterile THD Anoscope,Proctoscope, Rectoscope and Light-scope is a single-use anoscope with integrated LED lighting, suitable for performing diagnostic and operational anoscopes..</td><td>Identical</td></tr>
<tr><td>Operation Principle</td><td>WellCare Anoscope opens up the anal passage and then exits the anus, and the anal passage is continuously visualized by the speculum, and Sleeve fixes the perianal tissue at a certain angle during PPH and RPH hemorrhoid surgery, leaving a space and angle suitable for the operation. Thus, it can be used as an auxiliary instrument for hemorrhoid surgery</td><td>Gently press the The ANOSCOPES into the anus and slowly enter, then pull out the core, adjust the light, and slowly exit from deep to shallow，The compact and asymmetricaldesign of the THD Surgy MaxiLED allows easy access to the analcanal without sphincter traumaensuring good dilation and anexcellent view of the operatingfield</td><td>Identical</td></tr>
<tr><td>Design</td><td>WellCare Anoscope is composed of Anoscope, Introducer and Sleeve,a disposable illuminator and approved light source.</td><td>The LightScope LED anoscope combines ina single device a light anoscope and LED light source.</td><td>Different Comment 1</td></tr>
<tr><td>Anoscope material</td><td>medical polymer material PC</td><td>medical polymer material PC</td><td>Identical</td></tr>
<tr><td>Size （Unit：mm）</td><td><table><tr><td>Anoscope</td><td>Introducer</td><td>Sleeve</td></tr></table></td><td><table><tr><td colspan="2">BEVELLED</td><td colspan="2">TRUNCATED</td></tr><tr><td>diamet</td><td>lengt</td><td>diamet</td><td>lengt</td></tr></table></td><td>Different Comment 1</td></tr>
</table>

	diameter	length	diameter	Height	diameter	er	h	er	h	
						25	70	25	70	
	28.4±1	41.1±1	28±1	/	/	21.7	91	21.7	91	
						25.8	91	25.8	91	
	28.4±1	41.1±1	28±1	114±2	26±1	15	65	15	65	
	28.4±1	41.1±1	/	114±2	26±1	22	90	22	90	
						26	90	26	90	
	19.9±1	80.2±1	19.5±1	/	/					
Anoscope Packaging	sealed bag，Individually packaged					sealed bag，Individually packaged				Identical
Sterilization method	Sterilized by Ethylene Oxide					Sterilized by Ethylene Oxide				Identical
Light	a disposable illuminator and approved light source.					Self-light, with an integrated light source				Different Comment 1
Singe Use Only	disposable					disposable				Identical
Shelf Life	2 years					2 years				Identical

Comment 1

The Design of the two are only different ,For example, in terms of size, dimensions, and light source design,But the actual intended use is the same, which does not affect the safety and effectiveness of the product.

Comment 2

The light source of the two are different,But the function is the same Therefore, the safety and effectiveness of the product will not be affected.

VII Summary of Non-clinical Testing (Bench)

The non-clinical testing for WellCare Anoscope was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and recognized consensus standards shown below.

Table VII-1: Performance testing was conducted on the subject device

ID#	Test	Method	Acceptance Criteria	Conclusion
1	**Appearance**			
	Appearance	The shapeshouldbesmoothandsymmetrical, with nosharp edgesand no burrs in all parts.Themirror tube should be rounded, witha smooth inner walland a roundededgeatthewithouth eadend,burrs.	Smooth surface of all parts no sharp edges,no burrs.	Pass
2	**Physical Testing of Anoscope**			
2.1	compatibility	Take 1 set of samples and test them manually	The anal expander and the guide mirror opened and closed easily with the scope, without swing and jam. The end of the anal expander should be smooth and anastomosed with the endoscope, and the maximum gap should not be greater than 0.6mm.	Pass
2.2	Material strength	Take 1 set of samples, place the assembly horizontally and hang a 4 kg suspension in the middle of the assembly in accordance with the requirements	Any of the components (excluding the light source) should be able to withstand a 4 kg suspension without significant deformation	Pass
3	**Chemical Testing of Anoscope**			
3.1	Reducing substances (oxide prone)	The sample was taken, configured at a ratio of 0.1g plus 1mL of water and then thermostated at 37°C ± 1°C for 8h, the sample was separated from the liquid and cooled to room temperature as the test solution. Take the same volume of water in a glass container and prepare a blank control solution by the	The difference in the volume of potassium permanganate solution [c(1/5KMnO4) = 0.01 mol/L] consumed by the test solution and the blank control solution should not exceed 2.0 mL	0.4ml

		same method		
3.2	pH	Take the test solution of 3.1 and the blank control solution and determine their pH values respectively with an acidity meter	he difference between the pH of the test solution and that of the blank control solution should not exceed 1.5	1.01
3.3	EO/ECH residues	ISO 10993-7:2008	average daily dose to patient EO < 4 mg, ECH < 9mg	Pass
3.4	Sterile	ISO 11135:2014	WellCare Anoscope should be sterile	Pass
4	**Biocompatibility Testing**			
4.1	In Vitro Cytotoxicity	ISO 10995-5:2009	Non-cytotoxic	Pass
4.2	Skin Sensitization Test	ISO 10993-10:2021	Non-sensitizer	Pass
4.3	Acute Systemic Toxicity Test	ISO 10993-11:2017	No systemic toxicity	Pass
4.4	Pyrogen Test	ISO 10993-11:2017	Non-pyrogen	Pass
4.5	Irritation Test	ISO 10993-23:2021	Non-Irritation	Pass

VIII Clinical Test Conclusion

No clinical study is included in this submission.

IX Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the WellCare Anoscope is as safe as effective, and performs as well as or better than the legally marketed device.