January 10, 2018

Privi Medical Pte Ltd
% Alan Donald, MS, MBA, RAC
President
Matrix Medical Consulting, Inc.
8880 Rio San Diego Drive, Suite 800
San Diego, CA 92108

Re: K172358
Trade/Device Name: Instalief
Regulatory Class: Unclassified
Product Code: LKX
Dated: December 16, 2017
Received: December 19, 2017

Dear Alan Donald:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K172358

Device Name
Instalief

Indications for Use *(Describe)*
Instalief is a single use device for the treatment of hemorrhoids by applying it directly to the swollen hemorrhoidal tissues. By applying cold to the tissue, the inflammation is reduced. The device can be used for the treatment of external hemorrhoids and internal hemorrhoids. The device is for adults only.

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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Privi Medical Pte Ltd
Instalief™
Traditional 510(k)
Section 5 - Summary of Safety and Effectiveness

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1. Submitter's Information:

Company Name: Privi Medical Pte. Ltd.
Company Address: 79 Ayer Rajah Crescent #05-03, Singapore 139955
Company Phone Number: (415) 906-5188 (USA)
Contact: Mr. Prusothman M Sina Raja, CEO
Establishment Registration Number: Not yet obtained.

Device Trade Name: Instalief™
Common Name: Hemorrhoid Cooling Device
Classification Name: Device, Thermal, Hemorrhoids (LKX)
Product Code: LKX

2. Authorized Contact Person:

Name: Prusothman M Sina Raja
Email: prusothman@privimedical.com, prusothman@gmail.com
Telephone: (65) 93393513 (Singapore) / (415) 906-5188 (USA)

3. Company Device Information:

Device Name: Instalief™
Classification: Unclassified (Pre-Amendment)

4. Predicate Device Information:

Device Name: ANUICE
Cryotherapy Pain Relief Products, Inc.
Classification: Unclassified (Pre-Amendment)
510(k): K981428
Product Code: LKX

5. Submission Information:

Date Summary Prepared: 11th July 2017
Prepared by: Prusothman M Sina Raja

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6. Device Description

Instalief™ is a device designed for the treatment of internal and external hemorrhoids by the application of cold directly to the swollen hemorrhoidal tissue.

The device consists of an outer bag which houses an endothermic salt, a smaller water-containing frangible bag, an insertion tip with an attached compliant balloon, as well as a separate component that aids in the usage of the device, known as the squeezer.

To use the device, the user first bursts the frangible bag by pressing on it, initiating an endothermic process between the water and endothermic salt. The user then inserts the shaft of the device into the anal canal (for internal hemorrhoids) or applies to the outer tissues (for external hemorrhoids), and squeezes the bag with the aid of the squeezer. This action transfers the cold fluid generated into the balloon, which provides targeted cold therapy to the hemorrhoids. Instalief™ is meant to be used for 6 – 8 minutes.

In terms of physical characteristics, Instalief™ is anatomically designed by taking into account human anatomical characteristics. The introducer and balloon, which comes into contact with the user, is made from medical-grade material and conforms to the biocompatibility requirements of the device class. The introducer has filleted edges and a tapered shaft for smooth insertion into the anal canal. It is also designed with a functional length long enough to reach the internal hemorrhoids, as well as a flared base to physically prevent over-insertion. The balloon dimensions were chosen to allow for safe inflation without compromising the integrity of the material.

7. Indications for Use

Instalief™ is a single use device for the treatment of hemorrhoids by applying it directly to the swollen hemorrhoidal tissues. By applying cold to the tissue, the inflammation is reduced. The device can be used for the treatment of external hemorrhoids and internal hemorrhoids. The device is for adults only.

8. Substantial Equivalency

Instalief™ is substantially equivalent to Anuice and raises no new safety or effectiveness issues.

8.1. Non-Clinical Testing

The following tests were performed on Instalief™ and the predicate device (where applicable), for the comparison of functional performance and evaluation

of both structural integrity and biocompatibility.

Structural Integrity	
Performance Documentation (Test Protocols)	**Summary of Results**
Inflated Static Load Pull Test - *VV0001P*	Passed
Balloon Burst Volume Test - *VV0002P*	Passed
Compression Test (Against Predicate) - *VV0007P* - *VV0009P*	Both Devices Passed
Functional Performance	
Performance Documentation (Test Protocols)	**Summary of Results**
Cold Duration Test (Against Predicate) - *VV0003P* - *VV0008P*	Cold duration similar to predicate
Biocompatibility	
Test Information and Details	**Summary of Results**
In-vitro cytotoxicity – Elution method	Non-cytotoxic
Skin sensitization test in guinea pigs (guinea pig maximization test)	Non-sensitizing
Intracutaneous reactivity test in New Zealand white rabbits	Non-reactive

8.2. Clinical Testing

Clinical testing is not applicable for establishing substantial equivalence of Instalief™.

8.3. Comparison Table of New and Predicate Device

	Features and Specifications	**Instalief™**	**Anuice**	**Notes**
1	Mode of action	Application of cold to hemorrhoidal tissue	Application of cold to hemorrhoidal tissue	Same
2	Max insertion	Up to 25mm into	Up to 45mm into	Smaller initial insertion

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Section 5 - Summary of Safety and Effectiveness

	depth	the anal canal (for internal hemorrhoids)	the anal canal (for internal hemorrhoids)	depth for Instalief™
3	Max working depth	Up to 55mm into the anal canal (for internal hemorrhoids)	Up to 45mm into the anal canal (for internal hemorrhoids)	Both depths are in similar range. The slightly deeper working depth ensures better coverage of hemorrhoidal region.
4	Insertion depth limiter	Flared base component	Flared base component	Same. Both designed to physically limit insertion depth.
5	Insertion OD	7 mm (without balloon inflation) 30 mm maximum (with balloon inflation)	11mm	A smaller insertion OD allows for easier and more comfortable insertion and removal. The balloon is expanded after insertion into the anal canal, and is deflated prior to being withdrawn.
6	Cold source	Chemical (endothermic process)	Physical (phase change)	Similar. In Instalief™, the cold source is generated through an endothermic reaction, while the predicate device achieves this through a physical change of state of its contained substance. Both devices function using the principle of cold therapy.
7	Shaft material	Silicone Rubber (introducer)	Rigid plastic	Soft flexible shaft reduces the risk of tissue damage caused by erroneous insertion technique
8	Cold therapy delivery	Delivered via a compliant balloon	Delivered via a hollow shaft	The balloon is a better cold therapy delivery component as it conforms to the shape of the anal canal
9	Removal mechanism	Deflate balloon followed by withdrawal	Withdrawal of device	Similar
10	Base	PVC Bag	Hard plastic	Bag is designed to

				withstand the require back pressure during usage (see VV0007P)
11	Anatomically designed	Yes. General design characteristics: 1. Tapered shaft extending into anal canal 2. "Base" feature to prevent over-insertion of device 3. Smooth rounded corners 4. No sharp edges	Yes. General design characteristics: 1. Tapered shaft extending into anal canal 2. "Base" feature to prevent over-insertion of device 3. Smooth rounded corners 4. No sharp edges	Same. Similar design characteristics meant to facilitate insertion into/removal out of the anal canal.

8.4. Studies Cited for Substantial Equivalence Discussion

8.4.1. Ratuapli, M. D. et al.(2013). Comparison of rectal balloon expulsion test in seated and left lateral positions. *Neorugastroenterol Motil.* 25(12). Doi:10.1111/nmo.12208

8.4.2. Padda, B. S. et al. (2006). Effects of pelvic floor muscle contraction on anal canal pressure. *Am J Physiol Gastrointest Liver Physiol.* 292: G565-G571. Doi:10.1152/ajpgi.00250.2006

8.4.3. Duthie, H. L., Bennett, R. C. (1963). The relation of sensation in the anal canal to the functional anal sphincter: a possible factor in anal continence. *Gut,4, 179-182.* Doi:10.1136/gut.4.2.179

8.5. Referenced Devices

8.5.1. GelPOINT Path Transanal Access Platform (K133393)

9. Conclusion

Based on the comparison of intended use, indications for use, non-clinical testing, literature, biocompatibility testing and technological characteristics, the Instalief™ is substantially equivalent to Anuice (K981428) and raises no new safety or effectiveness issues.