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

August 30, 2017

Cry IQ AB
% Ms. Cherita James
Regulatory Consultant
M Squared Associates, Inc
515 Eight Avenue, St. 1212
New York, New York 10018

Re: K172049
Trade/Device Name: CryoIQ MULTI LINE
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: July 5, 2017
Received: July 6, 2017

Dear Ms. James:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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)*

K172049

Device Name
CryoIQ Multi LINE

Indications for Use *(Describe)*
The CryoIQ Multi LINE are reusable devices intended to destroy tissue during surgical procedures by applying extreme cold.

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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K172049

In accordance with 21 CFR 807.92, the following information constitutes the CryoIQ AB summary for the CryoIQ Multi LINE.

I. Submission Date

August 28, 2017

II. Submitter

Name:	CryoIQ AB
Address:	Apelrödsvägen 1
	439 32 Onsala
	Sweden
Contact person:	Stefan Skafte, President
Phone number:	+46 31-400 500
Fax number:	+46 300-56 94 99

III. Device

Name of device:	CryoIQ MULTI line
Common or usual name:	Cryosurgical unit & accessories
Classification name:	Cryosurgical unit & accessories
Regulatory class:	Class II per regulations 878.4350
Classification code:	GEH
Panel:	General & plastic surgery

IV. Predicate devices

	510(k)	Company	Device
Primary predicate	K091721	New Medical Technologies GmbH	CryoSuccess
Reference	K024009	H&O Equipments NV/SA	CryoProbe-C
	K102006	STC Consulting LLC	CryOmega

V. Device Description

The CryoIQ devices consist of a unit body with a lever and an applicator (capillary tube, tip). A disposable cartridge filled with nitrous oxide (N_2O, laughing gas) will be attached to the unit body by slightly screwing into it. The cartridge has a build-in valve for safety storage and release of the gas.

The CryoIQ designed to dispense a continuous stream of liquid nitrous oxide when actuated by pressing the lever.

The device functions by means of heat evaporation upon phase transition where the nitrous oxide is applied to the treatment area by means of the applicator (capillary tube, tip) at a constant temperature of -89°C/-128°F (cold performance) followed by evaporation. Physicians or medical professionals can use the gas in procedures requiring the destruction of tissue using the extreme cold of nitrous oxide (-89°C/-128°F).

VI. Intended use

The CryoIQ Multi LINE are reusable devices intended to destroy tissue during surgical procedures by applying extreme cold.

VII. Comparisons of the technological characteristics with the predicate device

CryoIQ MULTI line exists of 3 devices, CryoIQ DERM, CryoIQ PRO, CryoIQ EquiMed. They all have the same intended use to destroy tissue during surgical procedures by applying extreme cold, same technical features but they differ in design.

	Subject device	**Predicate Device**	**Reference devices**		**S.E**
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
Device Name	**CryoIQ MULTI line**	**CryoSuccess**	**CryoProbe-C**	**CryOmega**	
Models	CryoIQ DERM CryoIQ PRO CryoIQ EquiMed Std tip (ø 1mm) Dermatology tip (ø 2mm) Dermatology tip (ø 3mm) Dermatology tip (ø 4mm) Derm. tip, White (ø 1mm) Derm. tip, Blue (ø 2mm) Derm. tip, Green (ø 3mm Long tip 13 cm Angled tip 45°	CryoSuccess Std tip (ø 1mm) Std tip (ø 2mm) Std tip (ø 3mm) Std tip (ø 4mm) Gynecology tip	CryoProbe l c CryoProbe l x	CryOmega	

	Subject device	**Predicate Device**	**Reference devices**		**S.E**
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
Indication for use	To destroy tissue during surgical procedures by applying extreme cold.	To destroy tissue during surgical procedures by applying extreme cold	To destroy tissue during surgical procedures by applying extreme cold	Surgical destruction of target tissue by applying cryogenic gases at extreme low temperatures. The list below shows examples of the type of lesions that can be treated: -Genital lesions -Molluscum Contagiosum -Verruca Plantaris -Verruca Plana -Actinic Keratosis -Seborrheic Keratosis -Skin Tags -Lentigo	Yes
Type of lesions to be treated	-Genital lesions -Molluscum Contagiosum -Verruca Plantaris -Verruca Plana -Actinic Keratosis -Seborrheic Keratosis -Skin Tags -Lentigo	Not stated	Not stated	-Genital lesions -Molluscum Contagiosum -Verruca Plantaris -Verruca Plana -Actinic Keratosis -Seborrheic Keratosis -Skin Tags -Lentigo	Yes
Nitrogen	Nitrous Oxide (N_2O, laughing gas). Available in 16 g, 25 g and 40 g cartridge.	Nitrous Oxide (N_2O, laughing gas). Available in 23.5 g cartridge.	Nitrous Oxide (N_2O, laughing gas). Available in 8 g or 16 g cartridges.	Nitrous Oxide (N_2O, laughing gas). Available in 16 g cartridge.	Yes
	Cartridge pressure: 50 bar (725 psi)	Cartridge pressure: 50 bar (725 psi)	Cartridge pressure: 50 bar (725 psi)	Cartridge pressure: 50 bar (725 psi)	Yes

	Subject device	**Predicate Device**	**Reference devices**		**S.E**
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
	Shelf life: 2 years	Shelf life: 2 years	Shelf life: 2 years	Shelf life: 2 years	Yes
Shelf life Device	5 years	5 years (with 2 years warranty)	2 years	Disposable unit, is discarded after liquefied gas is emptied	Yes
Treatment Temperature	Liquid freezing: -89°C/-128°F constant temp.	Liquid freezing: -89°C/-128°F constant temp.	Liquid freezing: -89°C/-128°F constant temp.	Liquid freezing: -89°C/-128°F constant temp.	
Material	Housing: Cryo device has no housing. The device material is brass and stainless steel, gold plated Cryo tip: metal, gold plated, cryo tip in borosilicate glass 3.3 (such as DURAN) Lock cap: Plastic Filter: Stainless steel O-rings/Seals PTFE and acrylonitrile-butadiene-rubber Nitrous oxide cartridges: Metal	Housing: Cryo device has no housing. The device material is brass and stainless steel, gold plated Cryotip: metal, gold plated, cryotip in borosilicate glass 3.3 (such as DURAN) Protective Cap: Thermoplastic rubber Filter: Stainless steel O-rings/Seals PTFE and acrylonitrile-butadiene-rubber Nitrous oxide cartridges: Metal	Housing: Aluminum Micro-Applicator: Unknown Lock cap: Plastic Filter: Unknown O-rings/Seals: Unknown Nitrous oxide cartridges: Metal	Housing: plastic Micro-Applicator: Unknown Lock cap: Unknown Filter: Plastic O-rings/Seals Butadiene-rubber Nitrous oxide cartridges: Metal	Yes Yes Yes Yes Yes Yes
Mode of Use	Apply spray topically	Apply spray topically	Apply spray topically	Apply spray topically	Yes
Storage Conditions	Protect the unit against heat and exposure to direct sunlight. The storage temperature is between -10°C/14°F and	Protect the unit against heat and exposure to direct sunlight. The storage temperature is between -	Store in a cool dry place and keep out of reach of children, <50°C/122°F	<50°C/122°F	Yes

	Subject device	**Predicate Device**	**Reference devices**		**S.E**
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
	max. 50°C/122°F.	10°C/14°F and max. 45°C/113°F.			
Cleaning	The unit body and cryo tip can be cleaned and disinfected with an alcohol-based disinfectant or alcohol.	The unit body and cryo tip can be cleaned and disinfected with an alcohol-based disinfectant or alcohol.	All external parts can be wiped with a cloth soaked in any non-corrosive sterilization solution or alcohol.	Unknown	Yes
Sterilization	N/A	Steam sterilize applicators at 134°C/273°F, according to the instruction in the manual of your steam sterilizer and according to the country specific law	N/A	N/A	Yes
Safety	Complies with ASTM: F882-84 for Cryosurgical Medical Instrument	Complies with ASTM: F882-84 for Cryosurgical Medical Instrument	Complies with ASTM: F882-84 for Cryosurgical Medical Instrument	Complies with ASTM: F882-84 for Cryosurgical Medical Instrument	Yes
Operating Principle	CryoIQ functions by means of heat evaporation upon phase transition where liquid nitrous oxide (N_2O, laughing gas) is applied to the treatment area by means of a capillary tube (applicator, tip) at a constant temperature of -89°C/-128°F (cold performance) followed by evaporation. This results in cellular destruction (necrosis) in the treatment area. The amount of gas dispensed is controlled by the medical professional	Cryosuccess functions by means of heat evaporation upon phase transition where liquid nitrous oxide (N_2O, laughing gas) is applied to the treatment area by means of a capillary tube (applicator, tip) at a constant temperature of -89°C/-128°F (cold performance) followed by evaporation. This results in cellular destruction (necrosis) in the treatment area. The amount of gas dispensed is controlled by the medical professional Pressing the lever of the device.	The patented principle of the CryoProbe is based upon the direct flow of N_2O in liquid phase for the purpose of freezing with resulting in necrosis of tissue in the practice of medicine. To achieve this phenomenon an economical gas cartridge is used. The cartridge is filled with liquid N_2O (83%) and the rest with N_2O gas. The liquid N_2O is the	Gas dispensed using actuator lever. Spray controlled by on/off actuator.	Yes

	Subject device	**Predicate Device**	**Reference devices**		**S.E**
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
	Pressing the lever of the device.		refrigerant and the N_2O gas is the propellant. The innovation of the CryoProbe is the ability to achieve a constant flow of liquid N_2O out of the micro-applicator tip. This is made possible by maintaining the pressure level within the instrument until the liquid N2O leaves the tip of the micro-applicator, whereupon it will immediately expand.		
	Apply spray topically N_2O gas is delivered to the treatment site at -89°C/-128°F in order to cause cellular destruction.	Apply spray topically N_2O gas is delivered to the treatment site at -89°C/-128°F to in order to cause cellular destruction.	Apply spray topically N_2O gas is delivered to the treatment site at -89°C/-128°F to in order to cause cellular destruction.	Apply spray topically N_2O gas is delivered to the treatment site at -89°C/-128°F to in order to cause cellular destruction.	Yes
Maintenance	No maintenance required, repairs may only be executed by a licensed distributor or dealer.	No maintenance required, repairs may only be executed by a licensed distributor or dealer.	Change filter with each cartridge, exchange O-rings after frequent use.	Disposable once liquefied gas is emptied. No servicing.	Yes
Disposal	Unit body (Main unit) is reusable wit replaceable gas cartridge.	Main unit is reusable with replaceable gas cartridge.	Main unit is reusable with replaceable gas cartridge, filter needs to	Whole unit is disposable after liquefied gas is	Yes

	Subject device	Predicate Device	Reference devices		S.E
510(k)	**No number yet**	**K091721**	**K024009**	**K102006**	
510(K) sponsor	**CryoIQ AB**	**New Medical Technologies GmbH**	**H&O Equipments NV/SA**	**STC Consulting LLC**	
			be replaced when changing gas cartridge.	emptied from the cartridge.	

VIII. Performance testing

The CryoIQ has the same intended use as the predicate cryogenic devices that is intended for the destruction of tissue during surgical procedures by applying extreme cold caused by the use of nitrous oxide. The CryoIQ has the same technological characteristics as the predicate cryogenic device which sprays liquid nitrous oxide gas.

The predicate cryogenic device is using a lever to dispense the nitrous oxide gas from a cartridge thru a capillary tube. Therefore, technological differences between CryoIQ and its predicate device do not raise new questions about safety and efficacy.

The 510(k) notice includes data to verify that nitrous oxide in the CryoIQ device can safely and effectively cause destruction when used as instructed.

The CryoIQ Multiline performance has been tested according to Standard ASTM: F882-84 for Cryosurgical Medical Instruments.:

- Freezing Effect Evidence
- PPM test report
- Mechanical Integrity test report

The subject devices meet the requirements of the standard.

The freezing effect with the predicate device is comparable as same technology is used to dispense the nitrous oxide gas in liquid form. Bench performance test liquid freezing and gas consumption confirmed comparable performance when compared to the predicate.

IX. Conclusions

The information provided supports that the CryoIQ Multi LINE is substantially equivalent in function, composition, and intended use to the predicate device. The proposed device raise no new issues of safety and effectiveness. The non-clinical testing performed demonstrates that the proposed device met all test specifications and is suitable and safe for its intended use.