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

May 1, 2017

Soterix Medical,inc.
Abhishek Datta
Chief Technology Officer
237 W 35 St, 1401
New York, New York 10001

Re: K170291
Trade/Device Name: IontoDC
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: EGJ
Dated: January 31, 2017
Received: January 31, 2017

Dear Abhishek Datta:

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.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

As you are aware, there are concerns relating to the fact that no drug is currently labeled for administration via an iontophoresis device. The Agency currently is evaluating this public health concern regarding the safety and effectiveness of this route of administration of drugs, and in the near future will inform manufacturers of certain additional steps the Agency believes are necessary to address this concern.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 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 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K170291

Device Name
IontoDC

Indications for Use *(Describe)*
IontoDC is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.

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.

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
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Date Prepared: December 26, 2016

Submitter Information:

Company Name: Soterix Medical, Inc.
Company Address: 237 W 35 ST, 1401
New York, NY 10001
Contact Person: Abhishek Datta
Phone: 888-990-8327
Fax: 212-315-3232

Device Information:

Trade Name: IontoDC
Common Name: IontoDC
Classification Name: Iontophoresis Device (21 CFR 890.5525, Product Code EGJ)
Device Class: Class II

Predicate Device:

1. Dynatron® ibox Iontophoresis device (K043047)
   Dynatronics Corporation
   Class III (primary predicate)
2. ActivaDose II (K020476)
   Selective Med Components, Inc. acquired by Activatek Inc.
   Class III (reference device)

Device Description: IontoDC is a bench-top, battery powered, microcontroller-controlled iontophoresis device that delivers direct current to a drug delivery electrode placed on the patient's skin. This current expedites the migration of ionic drug solutions through the skin into localized tissue.

Intended Use: IontoDC is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.

Technological Comparison: IontoDC uses the same technological principle as the predicate device to accomplish its intended use, namely the introduction of ions to the body through direct current. The technology is based on the principle that an electric potential will cause ions in solution to migrate according to their

electrical charges. A technical comparison of the electrical output parameters of the device with the predicate device has been completed and supports a substantial equivalence determination.

Basis for Equivalence:

-Performance testing: Bench testing demonstrated that the electrical output parameters of the IontoDC device are substantially equivalent to those of the predicate device. The subject device complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC. Software verification and validation testing were conducted and documented per FDA's Guidance for Industry and Staff. The software for this device was considered as a "Moderate" level of concern.

-Labeling: The labeling of IontoDC device is substantially equivalent to that of the predicate device.

-Discussion of Clinical Tests Performed: Not Applicable.

Conclusions from Testing: The intended use and the basic technological characteristic of the IontoDC device are equivalent with those of the predicate device. The IontoDC device complies with the requirement of IEC 60601-1 and IEC 60601-1-2. Bench testing and safety report documentation supports the conclusion that electrical output is substantially equivalent to the predicate device, and any differences between the devices do not pose new questions of safety and effectiveness. Thus IontoDC device is substantially equivalent to the predicate device.

Parameter	IontoDC	ActivaDose II (Reference Device)	Dynatron® IBox (Primary Predicate)	Comparison
510(k)	To Be Determined	K020476	K043047	--
Device Name	IontoDC	ActivaDose II	Dynatron® ibox	--
Manufacturer	Soterix Medical, Inc.	ActivaTek. Inc.	Dynatronics Corporation	--

Parameter	IontoDC	ActivaDose II (Reference Device)	Dynatron® IBox (Primary Predicate)	Comparison
Indications For Use	IontoDC is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.	The ActivaDose II Iontophoresis Delivery Unit is indicated for the administration of soluble salts or other drugs into the body for medical purposes as an alternative to hypodermic injection in situations when it is advisable to avoid the pain that may accompany needle insertion and drug injection, when it is advisable to minimize the infiltration of carrier fluids, or to avoid the damage caused by needle insertion when tissue is traumatized.	Dynatron® ibox iontophoresis System is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.	**Identical to Primary Predicate**
Power source	Battery Powered	Battery Powered	Battery Powered	**Identical**
Number, Size, and Type of Batteries	Two 9 Volt Alkaline batteries	One 9V DC Alkaline Battery	Two 1.5 Volt AA Alkaline batteries	**SE** *Note 1*
Output Jacks	2	1	2	**Identical to Primary Predicate**
Current Intensity	1.0 - 2.0 mA DC	0.0 - 4.0 mA DC	0.5 - 4.0 mA DC	**SE** *Note 2*
Current Accuracy	+/- 1%	--	+/- 10%	**SE**

Parameter		IontoDC	ActivaDose II (Reference Device)	Dynatron® IBox (Primary Predicate)	Comparison
					Note 3
Current Precision		0.1 mA	0.1 mA	0.1 mA	**Identical**
Voltage at Electrodes		+/- 0-40 Volts	80 Volts	+/- 0-46 Volts	**SE** *Note 4*
Electrode Cable Jacks		Shielded banana	--	Custom 2-pin polarized	**SE** *Note 5*
Maximum Total Deliverable Dose		80 mA-min	80 mA-min	3360 mA-min	**Identical to Reference Device**
Single Treatment Deliverable Dose		10mA - 80 mA-min	0 - 80 mA-min	1 - 160 mA-min	**SE** *Note 6*
Number of 40 mA-min. Treatments		2	2	89	**Identical to Reference Device**
Minimum Treatment Time		10 min	1.5 seconds	15 seconds	**SE** *Note 7*
Maximum Treatment Time		40 min	20 minutes	100 minutes	**SE** *Note 8*
Timing Accuracy		+/- 3 second	+/- 1 second	+/- 1 second	**SE** *Note 9*
Polarity Options:	**Positive (+)**	YES	YES	YES	**Identical**
	Negative (-)	YES	YES	YES	**Identical**
	Dual Polarity	NO	NO	YES	**Identical to Reference Device**

Parameter		IontoDC	ActivaDose II (Reference Device)	Dynatron® IBox (Primary Predicate)	Comparison
	(+/-)				
Low Battery Warning:	**During Treatment**	YES	YES	YES, at 2.0 V remaining	**Identical**
	At Power-On	YES	YES	YES, if <2.2 V remaining	**Identical**
Overcurrent Warning		YES, if >2.2 mA	YES, at 4 mA	Yes, if >6 mA on any channel	**SE** *Note 10*
Certificates:	**IEC 60601-1**	YES		YES	**Identical**
	CSA/ NRTL	YES		YES	**Identical**
Dimensions (in.) [L x W x H]		7.91" x 5.9" x 2.83"	6.1" x 3.5" x 1.9"	4.5" x 2.66" x 1.25"	**SE** *Note 11*
Weight (lbs., oz.) [Without battery or electrode cables]		1 lb 3oz	.4 lbs	3.6 oz.	**SE** *Note 12*
Display		Digital Display	Digital Display	Organic Light Emitting Diodes (OLED)	**Identical to Reference Device**

Note 1:

The number of batteries used in subject device is different than the predicate device but all devices comply to IEC 60601-1 requirements. So the difference will not raise any safety issue.

Note 2:

The subject device can deliver a maximum of 2 mA of current as opposed to a maximum 4mA delivered by each of the predicates but all devices comply to IEC 60601-1 requirements. The differences in functional specifications will not raise any new safety and effectiveness issues.

Note 3:
The subject device has a current accuracy of 1% which is different than the 10% accuracy provided by the predicate. While both devices comply to IEC 60601-1 requirements, increased current accuracy in subject device ensures more accurate measurements. The differences in functional specifications will not raise any new safety and effectiveness issues.

Note 4:
The voltage provided by the subject device is slightly different than the predicate devices and is the lowest of all. All devices comply with IEC 60601-1 requirements so the differences in functional specifications will not raise any new safety and effectiveness issues.

Note 5:
The electrode cable jacks of the subject device is shielded banana while it is 2-pin polarized jack for the predicate device. Both jacks ensure a reliable connection so the difference does not raise new questions of safety and effectiveness.

Note 6:
The single treatment deliverable dose range for the subject device is slightly different than the predicate device. The upper limit of the total deliverable dose however does not exceed any of the predicate devices. This difference in functional specification will not raise any safety and effectiveness issue.

Note 7:
The minimum treatment time of the subject device is more than the predicate devices but this can be manually adjusted by pressing abort for any desired treatment time. This difference in functional specification does not raise any new safety and effectiveness issue.

Note 8:
The maximum treatment time of the subject device is more than one predicate device but less than the other. The treatment time can however be manually adjusted by pressing abort for any desired treatment time. This difference in functional specification does not raise any new safety and effectiveness issue.

Note 9:
The timing accuracy of the subject device is different than the predicate devices. This difference does not raise new safety and effectiveness issue for iontophoretic use.

Note 10:
The subject device can deliver a maximum of 2 mA and as a result the overcurrent warning threshold is is different than the predicate devices. This difference in functional specification will not raise a safety and effectiveness issue.

Note 11:
The subject device has different dimensions than the predicate devices. This difference in functional specification will not raise a safety and effectiveness issue.

Note 12:
The subject device has a different weight than the predicate devices. This difference in functional specification will not raise a safety and effectiveness issue.