July 27, 2018

ELITechGroup Inc.
Bryce McEuen
Managing Director and Business Unit Manager
370 W 1700 S
Logan, Utah 84321

Re: K180627
Trade/Device Name: Macroduct Advanced Model 3710
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis Device
Regulatory Class: Class II
Product Code: KTB
Dated: May 3, 2018
Received: May 7, 2018

Dear Bryce McEuen:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180627

Device Name
Macroduct Advanced Model 3710

Indications for Use *(Describe)*
The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.

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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Section 6.0 – 510(k) Summary

Date: July 27, 2018

Submitter: ELITechGroup Inc., dba Wescor Inc.
Address: 370 W 1700 S, Logan, UT 84321 USA
Phone number: 435-752-6011
Fax number: 435-752-4127

Contact: Bryce McEuen (Email: b.mceuen@elitechgroup.com)

Device name:

Trade/proprietary Name: **Macroduct® Advanced Model 3710**

Common or Usual Name: Macroduct Advanced Sweat Collection System

Code	*Name*	*Class*	*Regulation*	*Regulation Name*	*Panel*
KTB	Device, Iontophoresis, Specific Uses	II	21 CFR 890.5525	Iontophoresis Device	Physical Medicine

Establishment Information:

The establishment registration number for ELITechGroup Inc. USA is 1717966.
The owner operator number for ELITechGroup Inc. (Logan, UT, USA) is 1717966.

Predicate device:

Predicate Device	*510(k) Number*	*Product code(s)*
Macroduct® Model 3700-SYS	K853973	KTB

Device description:

The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.

The Macroduct Advanced Sweat Collection System consists of the Macroduct Advanced Model 3710, which is a microprocessor-controlled device powered from a rechargeable lithium-ion battery, battery charging power supply and cord for charging the battery, electrode cable assembly, and a kit of single-use supplies (Pilogel discs, collectors, and straps). The system safely and efficiently accomplishes the stimulation of human sweat through pilocarpine iontophoresis using the Macroduct Advanced Model 3710. The Macroduct Advanced Sweat Collector collects a sample of the stimulated sweat. Markings on the collection tube of the collector indicate if a sufficient sweat rate is achieved during the collection of sweat. The sample can then be analyzed for indications of cystic fibrosis with the Sweat-Chek™ Sweat Conductivity Analyzer using the principle of total electrolyte concentration in the sweat sample; or with the ChloroChek® Chloridometer® using the principle of coulometric titration.

The Macroduct Advanced cannot be used in combination with other medical devices.

Substantial Equivalence:

The Macroduct Advanced Model 3710 has demonstrated substantial equivalence to the predicate device, Macroduct Model 3700-SYS.

Similarities		
	Current Device Macroduct Advanced Model 3710	Previous Device Macroduct Model 3700-SYS
Indications for Use	The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.	Same
Iontophoresis current and time	Ramp (approximately 25 seconds) from 0 mA to 1.5 mA; hold at 1.5 mA for 5 minutes; ramp (approximately 5 seconds) from 1.5 mA to 0 mA.	Same
Pilogel Disc composition	0.5% pilocarpine nitrate in agar base.	Same

Similarities		
	Current Device Macroduct Advanced Model 3710	Previous Device Macroduct Model 3700-SYS
Pilocarpine transferred per test	Up to 1 mg	Same
Current Safety limit	Controlled by software/hardware to 1.5 mA, limited by hardware alone to <4 mA	Same
Iontophoresis power supply	Microprocessor controlled	Same
Sweat Collector material	High Impact Polystyrene (STYRON 478)	Same

Differences		
	Macroduct Advanced Model 3710	Predicate device Macroduct Model 3700-SYS
Sweat Collection area	.994 in^2 elliptical collection surface	.994 in^2 circular collection surface
Pilogel shape	Elliptical shape to match collector	Circular shape to match collector
Instrument Shell	Handheld, rounded rectangular in custom molded clamshell case in PC-ABS blend plastic	Handheld, rectangular, stock clamshell case in ABS plastic.
Instrument User interface	Touch screen with graphics showing step-by-step procedure, on-screen touch switch to start and stop iontophoresis, graphic indicator for current/low battery, audio signal for completion/error indication	Toggle switch to start and stop iontophoresis, LED indicators for current/low battery, audio signal for completion/error indication
Power Source	Three rechargeable 3.6 V Lithium ion batteries	Two 9V alkaline batteries

Modifications		
Characteristic	Modification	Rationale for Modification
Sweat Collection area	Changed the shape of the collection area from 0.994 in^2 round to 0.994 in^2 elliptical.	The collection area shape changed to elliptical to better fit limb skin surface, including small radius arms.

Modifications		
Characteristic	Modification	Rationale for Modification
Pilogel shape	Changed the Pilogel shape from round to elliptical.	The Pilogel shape was changed to match the elliptical shape of the collector.
Instrument Shell	The size, shape and material of the instrument shell changed.	To accommodate the touch screen
Instrument User interface	Touch screen with graphics showing step-by-step procedure, on-screen touch switch to start and stop iontophoresis, graphic indicator for current/low battery, audio signal for completion/error indication	Provide users with detailed visual instructions and information to further enhance and standardize the process of pilocarpine iontophoresis and sweat collection.

Performance Standards:

Regulation / Standard	Organization	Regulation / Standard Description
21 CFR 890.5525	US Code of Federal Regulations - FDA	Iontophoresis device intended for certain specified uses
C34-A3	CLSI	Sweat Testing: Sample Collection and Quantitative Chloride Analysis
IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012	IEC	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	IEC	Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
ANSI/AAMI ES60601-1:2005 / A2:2010	ANSI	US National Differences to IEC 60601-1:2005
EN 55022:2010	European Commission	Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement
47 CFR Part 15, Subpart B	US Code of Federal Regulations - FCC	Unintentional Radiators
ICES-003, Issue 6	Industry Canada	Information technology equipment – Radio disturbance characteristics – Limits and methods of measurement
ISTA 3A (2008)	ISTA	Packaged products for parcel delivery system shipments 70kg (150 lb) or less
Directive 2011/65/EU	European Parliament and the	Restriction of the use of certain hazardous substances in electrical and

	Council of the European Union	electronic equipment

Indications for Use:

The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.

Conclusion:

The modifications to the predicate device Macroduct Model 3700-SYS did not affect the use of the device or alter the fundamental scientific technology of the device. The design control process results for the Macroduct Advanced Model 3710 demonstrate that the Macroduct Advanced Model 3710 is substantially equivalent to the predicate device, Macroduct Model 3700-SYS, cleared under K853973.

The data demonstrates that the system is appropriate for its use and does not raise new issues of safety or effectiveness. A detailed summary of the verification, validation and risk analysis of these modifications are provided in Section 11 and complete risk analysis reports are provided in Appendix 1.