DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 16, 2016

Restorative Therapies Inc.
Scott Simcox
CTO
1434 Fleet Street
Baltimore, Maryland 21231

Re: K160614
Trade/Device Name: Xcite Clinical Station
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZI
Dated: November 22, 2016
Received: November 23, 2016

Dear Mr. Simcox:

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 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 yours,

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)*
K160614

Device Name
Xcite Clinical Station

Indications for Use *(Describe)*
The Xcite Clinical Station is intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion

The Xcite system is for prescription use 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.

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510(k) Summary

This 510(k) of Safety and Effectiveness information is prepared in accordance with the requirements of 21 CFR Part 807.92

(1) Submitter:

Andrew Barriskill
Restorative Therapies Inc
1434 Fleet St
Baltimore, MD 21231

Phone: 800 609-9166

Prepared on February 1, 2016.

(2) Device Name and Regulatory Classification:

Proprietary name:	Xcite Clinical Station ("Xcite")
Common name:	Powered Muscle Stimulator
Device Classification:	Class II
Classification name:	Powered Muscle Stimulator
Product code:	IPF (21 CFR 890.5850), GZI (21 CFR 882.5810)

(3) Predicate Device:

DANMETER A/S product: "Elpha 2000", K032954, a class II device
RESTORATIVE THERAPIES, INC. product: "RT300", K090750, a class II device

(4) Device Description:

Xcite is a multichannel Functional Electrical Stimulation (FES) system that delivers electrical stimulation to peripheral nerves in a coordinated fashion to facilitate various activities. The system is composed of:

1 A tablet computer
2 Up to two 6 channel stimulators
3 One or two stimulation cable(s) which connects the stimulator to cutaneous electrodes
4 cutaneous electrodes
5 an interface to a remote database for the storage and retrieval of therapy settings and the storage of therapy session logs
6 a mobile cart

(5) Statement of the intended use of the device:

Xcite is intended for general rehabilitation for:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
6. Maintaining or increasing range of motion

Xcite is for prescription use only.

THESE INDICATIONS FOR USE ARE THE STANDARD INDICATIONS FOR USE AS PER FDA GUIDANCE DOCUMENT "GUIDANCE DOCUMENT FOR POWERED MUSCLE STIMULATOR 510(K)S".

We have included the Elpha 2000 (K032954) as a second predicate device solely to demonstrate the additional two indications, number 4 and 5 above, which are not indications for use of RT300 (K090750).

(6) Technological Characteristics

The function of Xcite is the same as the predicate devices however there are certain technological similarities and differences as described below:

Technology	**Xcite**	**RT300 predicate: K090750**	**Elpha 2000 predicate: K032954**
Ergometer	No ergometer	Cycle ergometer	No ergometer
Power source (energy used)	Mains power and rechargeable battery for RT60 stimulators	Mains power and rechargeable battery for RT50 stimulators	Battery powered, alkaline or Ni-Cd
Controller	Based on tablet PC running custom software.	Based on Pocket PC running custom software.	Custom
Stimulator (energy delivered)	Up to 2 DC powered 0-140mA 6 channel charge balanced stimulators (“RT60”s).	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.	0-100mA 2 channels
Additional stimulation channels	N/A	Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.	N/A
FES parameters	0-140mA 50-500usec 10-100Hz	0-140mA 50-500usec 10-100Hz	0-100mA 200-400usec 2-100Hz
Stand alone stimulation mode	Always used in stand alone stimulation mode.	Wireless battery powered stimulation channels may be used in stand alone mode with out the cycle ergometer.	Always used in stand alone stimulation mode.
Stimwear garment	No stimwear garment.	Stimwear garment incorporating electrodes available for lower extremity cycling, ages 12 and above.	N/A
Muscles available for stimulation	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps,	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps,	Not specified.

Technology	Xcite	RT300 predicate: K090750	Elpha 2000 predicate: K032954
	anterior, posterior and middle deltoid, wrist extensors and flexors, grasp, abdominals, erector spinae.	anterior, posterior and middle deltoid, wrist, grasp, abdominals, erector spinae.	
Flywheel	N/A	Uses leg / arm crank motor to create flywheel effect with reduced weight and space.	N/A
Passive cycling	N/A	Utilizes motor to provide assistance during passive cycling.	N/A
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	No database.
Motorized arm crank	N/A	Allows active / passive arm cycling with FES	N/A
Pulse oximeter interface	N/A	Utilize pulse and SpO2 data for display, recording and alarming	N/A
Bilateral or Unilateral stimulation	Uses bilateral or unilateral stimulation.	Uses bilateral or unilateral stimulation.	Not specified.
Indications	1.Relaxation of muscle spasms 2.Prevention or retardation of disuse atrophy 3.Increasing local blood circulation 4.Muscle re-education 5.Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and	1.Relaxation of muscle spasms 2.Prevention or retardation of disuse atrophy 3.Increasing local blood circulation; and 4.Maintaining or increasing range of motion	1.Relaxation of muscle spasms 2.Prevention or retardation of disuse atrophy 3.Increasing local blood circulation 4.Muscle re-education 5.Immediate post-surgical stimulation of calf muscles to

Technology	Xcite	RT300 predicate: K090750	Elpha 2000 predicate: K032954
	6.Maintaining or increasing range of motion		prevent venous thrombosis; and 6.Maintaining or increasing range of motion

Table 1 Device technology comparison

(7) Performance data

Non-clinical testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	Description
Review of user documentation for predicate devices	Ensure that equivalent functionality is specified and implemented in the new device.
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables
Conduct of system testing	Conduct system testing to verify performance to specification.

Validation Testing	Description
Testing the Xcite Clinical Station	The Xcite Clinical Station with 12 stimulation channels was evaluated with five neurologically impaired individuals.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the Xcite Clinical Station. The system complies with Electromagnetic Compatibility and Electrical Safety
The Xcite system conforms to the following standards; IEC60601-1, ANSI/AAMI ES60601-1,IEC60601-1-2, IEC60601-1-11, and IEC60601-2-10.

RTI concludes that:

Xcite Clinical Station has the same intended use as the RT300 and Elpha 2000 predicate devices.

Xcite utilizes the same FES stimulators and stimulation control system as the RT300 predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

In conclusion, RTI's testing and validation testing has demonstrated that Xcite is as safe and effective as the predicate devices.