A final order reclassifying electroconvulsive therapy (ECT) indicated for use in treating catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, a preamendments Class III device, into class II (special controls), was published on December 26, 2018. See here: https://www.federalregister.gov/documents/2018/12/26/2018-27809/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-effective-date-of

This final order also required that that ECT devices intended for the following will remain Class III devices and would not be appropriate for the premarket notification pathway (510(k)), instead requiring a premarket approval (PMA): schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia or a severe MDE associated with MDD or BPD in:

i. Patients under 13 years; or

ii. Patients 13 years and older who are not treatment-resistant or who do not require a rapid response due to the severity of their psychiatric or medical condition.

While the device submitted and cleared through K960754 may serve as a valid predicate device for a new ECT device, please refer to the aforementioned final order for current regulatory requirements for this device type.

July 22, 2021

Mecta Corp.
Robin Nicol
President
7015 S.W. Mc Ewan Rd.
Lake Oswego, Oregon 97035

Re: K960754
Trade/Device Name: Spectrum 5000 Q, 5000 M, 4000 Q, 4000 M
Regulation Number: 21 CFR 882.5940
Regulation Name: Electroconvulsive therapy device
Regulatory Class: Class II
Product Code: QGH

Dear Robin Nicol:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 18, 1996. Specifically, FDA is updating this SE Letter to reflect an administrative correction corresponding to the reclassification of electroconvulsive therapy (ECT) intended to treat catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition, a preamendments class III device, into class II (special controls), as detailed in the final order published on December 26, 2018 (see here: https://www.federalregister.gov/documents/2018/12/26/2018-27809/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-effective-date-of). ECT devices intended for the following will remain Class III devices and would not be appropriate for the premarket notification pathway (510(k)), instead requiring a premarket approval (PMA): schizophrenia, bipolar manic states, schizoaffective disorder, schizophreniform disorder, and catatonia or a severe MDE associated with MDD or BPD in:

i. Patients under 13 years; or

ii. Patients 13 years and older who are not treatment-resistant or who do not require a rapid response due to the severity of their psychiatric or medical condition.

As a result of the final order, FDA has created a new product code (QGH) to better categorize ECT devices intended to treat catatonia or a severe major depressive episode (MDE) associated with major depressive disorder (MDD) or bipolar disorder (BPD) in patients age 13 years and older who are treatment-resistant or who require a rapid response due to the severity of their psychiatric or medical condition.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Pamela Scott, OHT5: Office of Neurological and Physical Medicine Devices, 301-796-5433, PamelaD.Scott@fda.hhs.gov.

Sincerely,

Vivek J. Pinto -S

Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 1996

Ms. Robin H. Nicol
Mecta Corporation
7015 S. W. McEwan Road
Lake Oswego, Oregon 97035

Re: K960754
Trade Name: Spectrum 5000 Q, 5000 M, 4000 Q, 4000 M
Regulatory Class: III
Product Code: 84GXC
Dated: June 7, 1996
Received: June 20, 1996

Dear Ms. Nicol:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

2

510(k) Number (if known): K960754

Device Name: spECTrum 5000 Q, 5000 M, 4000 Q, 4000 M

Indications For Use:

The intended use of the MECTA spECTrum device is solely for the treatment of "severe depression" or "major depressive episode with melancholia". (ref CFR Part 882 Part III). The clinical setting is in hospitla ECT suites, Operating Rooms, or on patient wards.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/12/96

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K960754

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use_____

(Optional Format 1-2-96)

SEP 18 1996

K960754

7015 SW McEwan Road
Lake Oswego, Oregon 97035
503/624-8778 FAX 503/624-8729

MECTA Corporation

PREMARKET NOTIFICATION SUBMISSION

510K SUMMARY

MECTA CORPORATION
7015 SW MCEWAN ROAD
LAKE OSWEGO, OR 97035
Telephone-(503) 624-8778
Fax-(503) 624-8729
CONTACT PERSON:
Robin H. Nicol, President
SIGNATURE Robin H. Nicol, President
2/21/96

SECTION ONE

a. NAME OF DEVICE-spECTrum 5000 Q, 5000 M, 4000 Q, 4000 M.
b. CLASSIFICATION DEVICE - Electroconvulsive Therapy Device.
c. ESTABLISHMENT REGISTRATION NUMBER- 3020533
d. ADDRESS OF MANUFACTURING FACILITIES
7015 SW McEwan Road
Lake Oswego, Oregon 97035
e. CLASS IN WHICH DEVICE HAS BEEN PLACED-Class III
f. REASON FOR PREMARKET MODIFICATION-New device which is substantially equivalent to the predicate device - K852069
g. IDENTIFICATION OF A LEGALLY MARKETED DEVICE TO WHICH CLAIM EQUIVALENCE- MECTA Models SR JR (same K# 852069)
h.NOT APPLICABLE

510K SUMMARY

IDENTIFICATION OF LEGALLY MARKETED DEVICE

The legally marketed devices MECTA SR and JR ECT devices are the current generation of MECTA devices that are substantially equivalent to the MECTA spECTrum 5000 and 4000 ECT devices.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The MECTA spECTrum 5000 and 4000 ECT devices * are the fourth generation of MECTA ECT devices and continue to be the state of the art ECT devices technically, while continuing to offer even more safety and efficacy clinically. The 5000 devices offer up to six channels of monitoring of ECG and EEG and one Optical Motion Sensor while the 4000 devices are only the ECT module of the 5000 devices. As such, they are upgradable to the 5000 series units and are identical to the SR JR series in their modularity (i.e.JR upgrade to SR, 4000 upgrade to 5000). The 5000 Q and 4000 Q offer the user flexibility with four stimulus parameters to vary energy and charge. The 5000 M and 4000 M offer the user simplicity with one single Stimulus Intensity knob which varies all four stimulus parameters simultaneously, again varying energy and charge.

The touch screen provides the user with an interface to set pre-treatment parameters. This provides the user with more flexibility as he can access all menus by simply touching a screen. The LCD which illuminates the touch screen provides the user with alphanumerics that talk him through through self-test, treatment, and monitoring of the EEG,ECG,and OMS. The LCD/touch screen includes choices of eight set-up menus in the 5000 series and one menu in the 4000 series that can help to individualize each patient's treatment in order to enhance the efficacy of each treatment. The LCD/ touch screen also provides the user with more data that can be recorded on the patient's record regarding the self test and treatment to ensure greater safety. Also, up to four channels of monitoring can be seen on the LCD-touch screen.

The two channel thermal chart recorder continues to provide the user with a hard copy of the self test and treatment results. The simplicity of the chart recorder only requires the user to set two gain knobs as the self test and treatment results are printed automatically. The manual on/off push button offers the user the option of manually controlling this printing also. The printout continues to provide two channels of monitoring and also provides the user with elapsed time, date, time of treatment, and patient name. The four stimulus parameters on the M series and Q series are also shown on the LCD/Touch Screen and the continuous updating of the percent energy on the M series also helps to increase efficacy of treatment.

Two features that offer the user enhanced safety during the self test and treatment are IEC 601-2-14 standards and as such are an advance. The hinged cover on the Stimulus Control push button prevents the user from accidentally treating. The Stimulus Status LED is illuminated to offer the user a visual confirmation that the spECTrum is enabled,that the stimulus is being delivered and finally indicates if there is a stimulus delivery fault. The three warning tones during self test and the constant tone during treatment continue to offer the user enhanced safety during the treatment process. The continuous self-test offers the user far greater accuracy in avoiding aborted or missed seizures as this bio-feedback provides him with acceptable ranges continuously which results in far greater efficacy.

the user far greater accuracy in avoiding aborted or missed seizures as this bio-feedback provides him with acceptable ranges continuously which results in far greater efficacy.

The data that can now be provided to the user with **two new MECTA features** affecting the safety and effectiveness of the treatment, now leads to even greater patient safety. The EEG data which provides analyses on seizure adequacy **and stimulus level ** will allow the clinician to better assess the quality and efficacy of each individual seizure.The predicate device that has been marketing seizure indices for a number of years is the Thymatron DGx marketed by Somatics Inc.(K#852069). The Optical Motion Sensor (OMS) will allow the user to monitor motor movement during the seizure and provide further valuable information in assessing seizure efficacy. The predicate device that has been marketing a motor monitor (EMG) for a number of years is the Thymatron DGx marketed by Somatics Inc. (K#852069).

The event timer, and the leads off information all provide added information for the clinician which allows him to better assess and improve clinical efficacy. The event timer is printed on the chart recorder as a permanent record. The leads off feature documents that the EEG or ECG leads are off and notifies the user by providing a message on the LCD Touch Screen.

All of the above features demanded the most advanced technical design to accommodate them as did the commitment to design to the most stringent domestic and international standards UL 544, CSA 22.2 125, and IEC 601- 1 (601-2-14 for electroconvulsive therapy devices), all of which resulted in far greater safety in the 4000 and 5000 devices to comply with these standards. The predicate devices SR/JR were UL,CSA listed and approved and partially approved to the IEC 601-1 standards. The spECTrum 5000/4000 devices are designed to the above UL,CSA, and TUV CE (IEC 601-1) standards. These approvals are pending and in process at this time. As such they are safer as the TUV standard is the most stringent safety agency internationally. These new devices include extensive redundant hardware and software testing and verification that they are operating correctly. The safety of these devices is unparalleled and as such are an advance that will impact the safety and efficacy of the ECT treatment dramatically.

As the technical advances have been a result of the field's demand for greater information, efficacy, and safety, the clinical advances have primarily been ongoing in the field over the last twenty-three years of MECTA's device history. Therefore, the MECTA 5000,4000 series will be used in a clinical setting with modified ECT that is identical to the setting that was used for the SR/JR,D, and C devices. Therefore, the clinical application of treating with the MECTA will remain the same. The 5000/4000 series continues to use the constant current bi-directional square waveform and the starter kit items accompanying these devices remains the same with the exception of the hand-held electrodes Again, these have been redesigned with all of the redundant safety that was designed into the new devices. The patents that are pending on the above features are identified with an asterik.
* US PATENT PENDING:
**US PATENT PENDING

THE INTENDED USE OF THIS DEVICE

The intended use of the MECTA spECTrum ECT device is solely for the treatment of "severe depression" or "major depressive episode with melancholia". (ref 21 CFR Part 882 Part III) The clinical setting is in hospital ECT suites, Operating Rooms, or on patient wards.