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MECTA Corporation

PREMARKET NOTIFICATION SUBMISSION

510K SUMMARY

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Robin H. Nicol, President

SIGNATURE

2/21/96

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FDA/CDER/DOE/DHC

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~~ *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 alphanumeric that talk him 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.

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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.