

K9605070

MAR - 6 1997

**SECTION ONE  
510K Summary**

- 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**-Device modification which is substantially equivalent to the predicate device - spECTrum 5000/4000 K960754
- g. **IDENTIFICATION OF A LEGALLY MARKETED DEVICE TO WHICH CLAIM EQUIVALENCE**- MECTA Models 5000 Q, 5000 M, 4000 Q, 4000M (same K# 960754)
- h. **NOT APPLICABLE**

## 510K SUMMARY

### IDENTIFICATION OF LEGALLY MARKETED DEVICE

The legally marketed devices are the MECTA Models 5000 Q, 5000 M, 4000 Q, and 4000 M ECT devices with parameter ranges identical to those of the MECTA SR and JR ECT devices.

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION

The enhanced MECTA spECTrum Models 5000 Q, 5000 M, 4000 Q, and 4000 M ECT devices\* will be identical to the currently legally marketed versions in every way except they will provide the clinician with slightly different parameter range options.

The spECTrum series products continue to be the state of the art ECT devices technically. 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 upgradeable to the 5000 series units. 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 frequency and duration 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 characters that lead 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 shown on the LCD/Touch Screen and the continuous updating of the percent energy on the M series helps to increase efficacy of treatment.

Several features designed to IEC 601-2-14 standards offer the user enhanced safety during the self test and treatment 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 measurements continuously which results in far greater efficacy.

The data that can now be provided to the user with the two new features of the spECTrum series now leads to even greater patient safety. The EEG data which provides analyses on seizure adequacy\*\* and stimulus level\*\* allows the clinician to better assess the quality and efficacy of each individual seizure. The Optical Motion Sensor (OMS) allows the user to monitor motor

movement during the seizure and provide further valuable information in assessing seizure efficacy.

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 demand the most advanced technical design to accommodate them and to meet the most stringent domestic and international standards UL 544, CSA 22.2 125, and TUV EC IEC 601-1 (601-2-14 for electroconvulsive therapy devices), all of which result in far greater safety in the 4000 and 5000 devices to comply with these 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. The spECTrum series 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. The 5000/4000 series continues to use the constant current bi-directional square waveform, while the starter kit includes improved hand-held electrodes. Again, these have been redesigned with the redundant safety features required to meet the above mentioned standards. Patents are pending on the features identified with an asterisk.

\* 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.