

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 K911144 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

Elcot, Inc.  
Ivan G. Schick  
14 East 60th St.  
New York, New York 10022

Re: K911144  
Trade/Device Name: MF-500, Modification  
Regulation Number: 21 CFR 882.5940  
Regulation Name: Electroconvulsive therapy device  
Regulatory Class: Class II  
Product Code: QGH

Dear Ivan Schick:

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 October 18, 1991. 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](mailto: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

OCT 18 1991

Food and Drug Administration  
1390 Piccard Drive  
Rockville MD 20850

Mr. Ivan G. Schick  
President  
ElCoT, Inc.  
14 East 60th Street  
New York, N. Y. 10022

Re: K911144C  
MF-500  
Dated: September 17, 1991  
Received: September 19, 1991  
Regulatory: Class III

Dear Mr. Schick:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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. In addition, the Food and Drug Administration (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 the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-1116. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Abhijit Acharya, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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