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 K863815 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: K863815
Trade/Device Name: Electroconvulsive Therapy Device, Model MF-1000
Regulation Number: 21 CFR 882.5940
Regulation Name: Electroconvulsive therapy device
Regulatory Class: Class II
Product Code: QGH

Dear Ivan G. 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 June 2, 1987. 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
8757 Georgia Avenue
Silver Spring MD 20910

JUN 2 1987

Re: K863815A
Electroconvulsive Therapy
Device, Model MF-1000
Dated: March 11, 1987
Received: March 17, 1987
Regulatory class: III

Elcot, Inc.
Attn: Ivan G. Schick
14 East 60th Street
New York, New York 10022

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 practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. 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 pre-amendments 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 anyway 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) 427-8040. 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,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology, and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological Health