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 K860467 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

Medcraft Corp.
Chyung
433 Boston Post Rd.
Darien, Connecticut 06820

Re: K860467
Trade/Device Name: Electroshock Unit Neurology Model B-25
Regulation Number: 21 CFR 882.5940
Regulation Name: Electroconvulsive therapy device
Regulatory Class: Class II
Product Code: QGH

Dear Chyung:

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 November 10, 1986. 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

NOV 10 1986

Re: K860467B
Electroshock Unit - Neurology
Unit Model B-25
Dated: August 27, 1986
Received: September 2, 1986
Regulatory class: III

Medcraft Corporation
Attn: C.E. Chyung
433 Boston Post Road
Darien, Connecticut 06820

Dear Mr. Chyung:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be 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 your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). This device has been placed into the regulatory class shown above, by a final regulation published in the Federal Register. All classes of devices are regulated by the general controls provisions of the Act applicable to all medical devices including annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act; class II devices must also meet present or future performance standards; class III devices will be required to undergo premarket approval at some time in the future. Please note: This action 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.

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. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

George C. Murray

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