November 13, 2024

Oriental Inspiration Limited
Francis Ko
Director
Unit D (01), 14/F.,Block 1,Tai Ping Industrial Centre,No. 57
Ting Kok Road, Tai Po,New Territories
Hong Kong, Hong Kong
China

Re: K233046
Trade/Device Name: Electrical Neuromuscular Stimulator, Cure Trio
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ, IPF, NGX, NUH, NYN, GZI

Dear Francis Ko:

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 April 19, 2024. Specifically, FDA is updating this SE Letter to correct the Rx/OTC designation as an administrative correction.

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,

Pamela D. Scott -S

Pamela D. Scott
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 19, 2024

Oriental Inspiration Limited
Francis Ko
Director
Unit D (01), 14/F.,Block 1,Tai Ping Industrial Centre,
No. 57 Ting Kok Road, Tai Po, New Territories
Hong Kong, Hong Kong
China

Re: K233046
Trade/Device Name: Electrical Neuromuscular Stimulator, Cure Trio
Models MC-310A, MC-310B, MC-310C, MC-310D,MC-310E, MC-310F, MC-310G
MC-310H, MC-310I, MC-310O, MC-310P, MC-310Q, MC-310R, MC-310S, MC-310T,
MC-310U
Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief, Powered muscle stimulator
Regulatory Class: Class II
Product Code: NUH,GZJ, IPF,NGX, NYN, GZI
Dated: March 11, 2024
Received: March 20, 2024

Dear Francis Ko:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Doe W. Kumsa -S

for Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233046

Device Name
Cure TrioModel: MC-310A

Indications for Use *(Describe)*

Cure Trio (Model: MC-310A), Rx and OTC
The Cure Trio MC-310A is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To stimulate healthy muscles in order to improve and facilitate muscle performance
[3] To relax muscle spasm
[4] To increase blood flow circulation
[5] For prevention of retardation of disuse atrophy
[6] For muscle re-education
[7] For maintaining or increasing range of motion

Cure TrioModel: MC-310B), Rx and OTC
The Cure Trio MC-310B is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To stimulate healthy muscles in order to improve and facilitate muscle performance
[3] To relax muscle spasm
[4] To increase blood flow circulation
[5] For prevention of retardation of disuse atrophy

Cure Trio (Model: MC-310C), Rx and OTC
The Cure Trio MC-310C is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles

[2] To stimulate healthy muscles in order to improve and facilitate muscle performance
[3] To relax muscle spasm
[4] To increase blood flow circulation
[5] For prevention of retardation of disuse atrophy

Cure TrioModel: MC-310D), Rx and OTC
The Cure Trio MC-310D is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management. It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain

Cure TrioModel: MC-310E, Rx and OTC
The Cure Trio MC-310E is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management. It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain

Cure TrioModel: MC-310FRx and OTC
The Cure Trio MC-310F is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2]Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To relax muscle spasm
[3] To increase blood flow circulation
[4] For prevention of retardation of disuse atrophy

Cure TrioModel: MC-310G) Rx and OTC
The Cure Trio MC-310G is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b.When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] For prevention of retardation of disuse atrophy

Cure TrioModel: MC-310HRx and OTC
The Cure Trio MC-310H is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management. It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities

(arms) and lower extremities (legs) due to strain from exercise or normal household duties

Cure TrioModel: MC-310IRx and OTC
The Cure Trio MC-310I is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To stimulate healthy muscles in order to improve and facilitate muscle performance

Cure TrioModel: MC-310ORx and OTC
The Cure Trio MC-310O is electrical stimulator designed for pain management and neuro muscular stimulation.
a.When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To stimulate healthy muscles in order to improve and facilitate muscle performance
[3] To relax muscle spasm
[4] To increase blood flow circulation
[5] For prevention of retardation of disuse atrophy
[6] For muscle re-education
[7] For maintaining or increasing range of motion

Cure TrioModel: MC-310PRx and OTC
The Cure Trio MC-310P is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management.
It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain

Cure TrioModel: MC-310QRx and OTC
The Cure Trio MC-310Q is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management.
It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain

Cure TrioModel: MC-310R) Rx and OTC
The Cure Trio MC-310R is electrical stimulator designed for pain management and neuro muscular stimulation.
a. When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis

[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To relax muscle spasm
[3] To increase blood flow circulation
[4] For prevention of retardation of disuse atrophy
[5] For muscle re-education
[6] For maintaining or increasing range of motion

Cure TrioModel: MC-310SRx and OTC
The Cure Trio MC-310S is electrical stimulator designed for pain management and neuro muscular stimulation.
a. When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b.When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To relax muscle spasm
[3] To increase blood flow circulation
[4] For prevention of retardation of disuse atrophy
[5] For muscle re-education
[6] For maintaining or increasing range of motion

Cure TrioModel: MC-310TRx and OTC
The Cure Trio MC-310T is Transcutaneous Electrical Nerve Stimulation device(Only TENS) for pain management. It is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties

Cure TrioModel: MC-310URx and OTC
The Cure Trio MC-310U is electrical stimulator designed for pain management and neuro muscular stimulation.
a. When using Cure Trio to deliver Transcutaneous Electrical Nerve Stimulation (TENS Mode), it is intended to provide:
[1] Symptomatic relief and management of chronic, intractable pain
[2] Relief of pain associated with arthritis
[3] Temporarily relieves pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arms) and lower extremities (legs) due to strain from exercise or normal household duties
[4] Relief of post-surgical pain and post traumatic acute pain
b. When using Electrical Muscle Stimulation (EMS Mode), Cure Trio is intended:
[1] To temporarily increase local blood circulation in healthy leg muscles
[2] To stimulate healthy muscles in order to improve and facilitate muscle performance

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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