November 3, 2023

ManaMed, Inc
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K231569
Trade/Device Name: ManaFlexx 2 (model: MF002-RX, MF002-OTC)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN, GZJ, IPF
Dated: May 25, 2023
Received: May 31, 2023

Dear Cassie Lee:

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,

Robert Kang -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K231569

Device Name
ManaFlexx 2(Model: MF002-RX, MF002-OTC)

Indications for Use *(Describe)*
For Over-The-Counter Use:
TENS:
ManaFlexx 2 (MF002-OTC) is used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.
ManaFlexx 2 (MF002-OTC) is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS/NMES:
ManaFlexx2 (MF002-OTC) is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.
ManaFlexx2 (MF002-OTC) is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

For Prescription Use:
TENS:
ManaFlexx2 (MF002-RX) is intended for the following use:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

PMS/NMES:
ManaFlexx2 (MF002-RX) is intended for the following use:
- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

1. Submitter's Information

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Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Date of the summary prepared: November 1, 2023

3. Subject Device Information

Common Name: Transcutaneous Electrical Nerve Stimulation (TENS) unit, Powered Muscle Stimulation (PMS) unit, blood circulation, and muscle performance
Trade Name: ManaFlexx 2
Classification Name: Stimulator, Nerve, Transcutaneous, Over-the-Counter
Model: MF002-RX, MF002-OTC
Regulatory Class: II
Product Code: NUH, NGX, NYN, GZJ, IPF
Regulation Number: 21 CFR 882.5890

4. Predicate Device Information

Predicate Device1 (Primary):

510(K) Number: K191151
Company Name: JKH USA, LLC
Address: 1142 S. Diamond Bar Blvd, #861, Diamond Bar, CA 91765
Trade Name: JKH Stimulator Plus
Model: PL-029K5BL, PL-029K15, PL-029T
Regulation Number: 21 CFR 882.5890\
Regulatory Class: II
Product Code: NUH, NGX, NYN, GZJ, IPF, IRT

Reference Device:
510(K) Number: K200237
Company Name: Shenzhen Kentro Medical Electronics Co., Ltd
Address: No.3, Xihu industry zone, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China
Trade Name: Transcutaneous Electronic Nerve Stimulator
Model: KTR-2401, KTR-2402, KTR-2411, KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342, KTR-2491, KTR-2492, KTR-2493, KTR-2494.
Regulation Number: 21 CFR 890.5850
Regulatory Class: II
Product Code: NUH

5. Device Description

The ManaFlexx 2 delivers electric pulse generated to the user's body areas through the electrodes. The device has two program modes of different pulse frequencies, covering TENS and PMS/NMES.
The main unit is egg shape, includes operating elements, such as the ON/OFF button, intensity increase button and intensity decrease button, and there are two snap connectors on the rear of the device which are for connecting with electrode. The device could be easily operated through its buttons to manually realize its functions, such as turning on/off and increasing/decreasing intensity, and there is a LED screen to display the selected mode, intensity level and charging status.
The electrode is a long strip shape with a size of 21cm x 5.3cm, its conductive part is black color, and there is white non-conductive area with a width of 1 cm in the middle, which divides the electrode into two parts: positive and negative. There are 2 snap connectors on the rear of the electrode used for connection with main unit.
The device has two models, both models have the same appearance, the identical hardware and software, only the model names are different and model MF002-Rx is for prescription use and MF002-OTC is for OTC use.

6. Intended Use / Indications for Use

For Over-The-Counter Use:

TENS:

ManaFlexx 2 (MF002-OTC) is used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

ManaFlexx 2 (MF002-OTC) is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS/NMES:

ManaFlexx 2 (MF002-OTC) is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

ManaFlexx 2 (MF002-OTC)is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

For Prescription Use:

TENS:

ManaFlexx 2 (MF002-RX) is intended for the following use:

- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

PMS/NMES:

ManaFlexx 2 (MF002-RX) is intended for the following use:

- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

7. Comparison to predicate device and conclusion

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Primary Predicate Device	Reference Device	Remark
Device Name and Model	ManaFlexx 2 (MF002-RX, MF002-OTC)	JKH Stimulator Plus (PL-029K5BL, PL-029K15, PL-029T)	Transcutaneous Electronic Nerve Stimulator (Model: KTR-2401, KTR-2402, KTR-2411,KTR-2412, KTR-2301, KTR-2302, KTR-2341, KTR-2342, KTR-2491, KTR-2492, KTR-2493, KTR-2494)	--
510(k) Number	K231569	K191151	K200237	--
Product Code	NUH, NGX, NYN, GZJ, IPF	NUH, NGX, NYN, GZJ, IPF, IRT	NUH	Similar Note 1
Intended Use	For Over-The-Counter Use: TENS: ManaFlexx 2 (MF002-OTC) is used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. ManaFlexx 2 (MF002-OTC) is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS/NMES: ManaFlexx 2 (MF002-OTC) is used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. ManaFlexx 2 (MF002-OTC)is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	Over-The-Counter Use: TENS: PL-029K5BL, PL-029K15, and PL-029T are used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. PL-029K5BL, PL-029K15, and PL-029T are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. The device of PL-029K5BL and PL-029K15 may be used during sleep. The device of PL-029K5BL and PL-029K15 is labeled for use only with its own compatible electrodes. PMS: PL-029K5BL, PL-029K15, and PL-029T are used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for	Transcutaneous Electronic Nerve Stimulator is indicated for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.	Similar Note 1

	For Prescription Use: TENS: ManaFlexx 2 (MF002-RX) is intended for the following use: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Relief of pain associated with arthritis PMS/NMES: ManaFlexx 2 (MF002-RX) is intended for the following use: - Temporary relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Muscle re-education - Maintaining or increasing range of motion - Increase of local blood flow in the treatment area - Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles	use in any therapy or for the treatment of any medical conditions or diseases. PL-029K5BL, PL-029K15, and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: The device of PL-029T is intended for temporary relief of minor aches and pains. Prescription Use: TENS: PL-029K5BL, PL-029K15, and PL-029T are intended for the following use: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Relief of pain associated with arthritis PMS: PL-029K5BL, PL-029K15, and PL-029T are intended for the following use: - Temporary relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Muscle re-education - Maintaining or increasing range of motion - Increase of local blood flow in the treatment area - Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles		
Prescription or OTC	OTC and Prescription	OTC and Prescription	OTC	Same
Power Source(s)	Rechargeable battery	Rechargeable or non-rechargeable battery	For KTR-23XX series: CR2032; 3Vdc; 240mAh For KTR-24XX series: PL301526; 3.7Vdc, 250mAh	Same
Method of line current isolation	Battery supply	Battery supply	Not public available	Same
Patient leakage current:	<10 μA	N/A	NC: DC: 0.5μA	Different

Normal condition (μA)				SFC: DC: 0.6μA	Note 2
Patient leakage current: Single Fault condition (μA)		<50 μA	N/A	Not public available	Different Note 2
Average DC current through electrodes when device is on but no pulses are being applied (mA)		0	0	< 0.01μA	Same
Number of Output Modes		2	PL-029K5BL: 6-8 PL-029K15: 1-4 PL-029T: 8	For KTR-23XX series: 3 modes For KTR-240X series & KTR-241X series: 3 modes For KTR 249X series: 15 modes	Different Note 3
Number of Output		1	1-2	1	Same
Synchronous/Alternating ?		N/A	N/A	Synchronous	Same
Method of Channel Isolation		N/A	N/A	Not public available	Same
Regulated Current or Regulated Voltage?		Voltage	Voltage	Voltage Control	Same
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Same
Automatic Overload Trip?		No	No	No	Same
Automatic No-Load Trip?		Yes	Yes	No	Same
Automatic Shut Off?		Yes	Yes	Yes	Same
User Override Control?		Yes	Yes	Yes	Same
Indicator display	On/Off status?	Yes	Yes	Yes	Same
	Low battery?	No	Yes	No	Same
	Voltage/current level?	Yes	Yes	Yes	Same
Time range (minutes)		30	PL-029K5BL: 10-540 PL-029K15: 10-60 PL-029T: 10-60	15 min	Similar Note 4
Compliance with Voluntary Standards?		Yes	Yes	Not public available	Same
Compliance with 21 CFR 898?		Yes	Yes	Not public available	Same
Weight (g)		17.8g	PL-029K5BL: 40 PL-029K15: 35	Main Unit:31g Electrode:	Similar Note 5

		PL-029T: 70	EPAD-H01: 13g, EPAD-H02: 13g, EPAD-F01:15g, EPAD-F02: 10g, EPAD-F03: 12g, EPAD-B01: 8g, EPAD-T01: 8g, EPAD-Z01: 55g	
Dimensions (mm) (L x W x D)	59.8*40*14.4mm	PL-029K5BL: 66x56x18 PL-029K15:70x62x16 PL-029T: 95x55x15	Model KTR-2401: Φ46.3x12.07; Model KTR-2402: Φ46.28x11.69 Model KTR-2411: 46.29x46.29x12.08; Model KTR-2412: 46.29x46.29x11.59; Model KTR-2301: Φ49.8x12.44; Model KTR-2302: Φ49.8x12.48 Model KTR-2341: 48.8x48.8x12.42; Model KTR-2342: 48.8x48.8x12.45; Model KTR-2491: Φ49.8x12.44; Model KTR-2492: Φ49.8x12.48 Model KTR-2493: 48.8x48.8x12.42; Model KTR-2494: 48.8x48.8x12.45;	Similar Note 5
Housing Materials and Construction	ABS plastic	Silicone & ABS	Main unit: ABS plastic	Same
Function and Design	Electrical stimulation	Electrical stimulation and heat	Not public available	Similar Note 1
Waveform	Biphasic	Biphasic	Pulsed, symmetric, biphasic	Same
Shape	Rectangular	Rectangular	Rectangular, with interphase interval	Same
Maximum output voltage at 500Ω	45 V ±10%	PL-029K5BL:65 ±20% PL-025K15: 36 ±20% PL-029T: 46 ±20%	43.6V±10% @ 500Ω	Similar Note 3
Maximum Output Voltage @ 2KΩ	80 V±10%	PL-029K5BL:132 ±20% PL-025K15: 72 ±20% PL-029T: 92 ±20%	59V±10% @ 2KΩ	Similar Note 3
Maximum Output Voltage @ 10KΩ	130V±10%	PL-029K5BL:180 ±20% PL-025K15: 125 ±20% PL-029T: 136 ±20%	66.5V±10% @ 10KΩ	Similar Note 3
Maximum Output Current @ 500Ω	90 mA ±10%	PL-029K5BL:130±20% PL-025K15: 72 ±20%	87.2mA±10% @ 500Ω	Similar Note 3

		PL-029T: 92±20%		
Maximum Output Current @ 2KΩ	40mA±10%	PL-029K5BL:66 ±20% PL-025K15: 36 ±20% PL-029T: 47 ±20%	29.5mA±10% @ 2KΩ	Similar Note 3
Maximum Output Current @ 10KΩ	13mA±10%	PL-029K5BL:18±20% PL-025K15: 12.5 ±20% PL-029T: 13.6 ±20%	6.65mA±10% @ 10KΩ	Similar Note 3
Pulse Width (μSec)	107	PL-029K5BL: 50~500 PL-029K15: 100 PL-029T: 104	120μs	Similar Note 3
Pulse period (mSec)	10~28.57	PL-029K5BL: 2~1000 PL-029K15: 10~1000 PL-029T: 6~833	Not public available	Similar Note 3
Frequency (Hz)	35-100	PL-029K5BL: 1~500 PL-029K15: 1~100 PL-029T: 1.2~167	20-100Hz	Similar Note 3
Maximum Phase charge (μC) at 500Ω	9.6	PL-029K5BL:78 PL-025K15: 14.5 PL-029T: 19.3	12.66μC @ 500Ω	Similar Note 3
Maximum average current density (mA/cm^2) at 500Ω	1.70	PL-029K5BL: 1.86 PL-029K15: 0.35 PL-029T: 0.40	0.058 (mA/cm^2)	Similar Note 3
Maximum average power density (mW/cm^2) at 500Ω	0.035	PL-029K5BL: 28 PL-029K15: 1.68 PL-029T: 2.22	0.037 (mW/cm^2)	Different Note 3
On time (sec)	Mode 1: 10 Mode 2: 5	1~20	Not public available	Similar Note 6
Off time (sec)	Mode 1: 7 Mode 2: 1.3	0~10	Not public available	Similar Note 6
Electrode aera	53cm^2	Not public available	Not public available	Different Note 7

Comparison in Detail(s):

Note 1:

The intended use of the subject device is the same as the primary predicate device K191151 and include the intended use of reference device K200237. But the Indication for use (IFU) differs slightly because the predicate 1 includes the heating function. So, the product code IRT is not included in this submission. The intended use for OTC and Prescription use is the same as the primary predicate device K191151. The difference does not have effect on the intended use.

Note 2:

The applied part of subject device is type BF, according to Table 3 of IEC 60601-1: 2020, the allowable values of patient leakage current under normal condition is less than 10 μA (d.c. current) and less than 10 50 μA under single fault condition (d.c. current). So, the subject device meets the requirement of IEC 60601-1. This difference will not raise safety issue.

Note 3:

The parameter of subject device is very close to the predicates:

- Maximum output voltage at 500Ω is close to primary predicate device K191151 and reference device K200237;
- Maximum Output Voltage at 2KΩ, Maximum Output Voltage at 10KΩ, Pulse Width (μSec) and Maximum average current density (mA/cm2) at 500Ω are close to the primary predicate device K191151;
- The pulse width as well as frequency are within the range of PL-029T of primary predicate device K191151.
- Maximum average power density (mW/cm^2) at 500Ω is close to the reference device K200237;

So, we think that the difference will not raise safety or effectiveness issue.

Note 4:

The “Time range” of subject device is 30 minutes, within the range of predicate device (10~60 min, or 10~540 min). And other performance parameter such as maximum output voltage and maximum output current are almost the same as the predicate device. So, the difference will not raise any safety or effectiveness issue.

Note 5:

Although the “Weight” and "Dimensions" are different from the predicate devices, the appearance will not have effect on the safety and effectiveness.

So, the difference will not raise any safety or effectiveness issue.

Note 6:

Although the “On time” and “Off time” are different from the predicate devices, but other performance parameter such as maximum output voltage and maximum output current are almost the same as the predicate devices. And the device meets the requirement of IEC 60601-2-10, so these differences will not raise any safety or effectiveness issue.

Note 7:

Though the electrode area of subject device may be different from that of predicate, but the result of Maximum average current density (mA/cm2) at 500Ω is close to primary predicate device K191151. And Maximum average power density (mW/cm2) at 500Ω is close to reference device K200237, and meet the requirement of FDA guidance “Guidance Document for Powered Muscle Stimulator 510(k)s - Guidance for Industry, FDA reviewers/Staff and Compliance”. So, the difference will not raise safety and effective issues.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance Testing Summary
The ManaFlexx2 (Model: MF002-RX, MF002-OTC) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device Description /Sample size	Test Method/Applicable Standards	Acceptance Criteria	Unexpected Results/ Significant Deviations	Test Result
General requirements for basic safety and essential performance	The test sample is the final, finished product.	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product.	IEC 60601-1-2 Edition 4.1 2020-09	No degradation of performance was found during test.	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	The test sample is the final, finished product.	IEC 60601-1-11 Edition 2.1 2020-07	The device operates normally, and can provide basic safety and essential performance.	NA	Pass
Requirements for the basic safety and essential performance of nerve and muscle stimulators	The test sample is the final, finished product.	IEC 60101-2-10 Edition 2.1 2016-04	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Dispersion and Shelf Life Test	The test sample is the final, finished	Measuring the resistance	The impedance change before the new and	NA	Pass

	product.	between each point in order to know the evenly distribute of the current based on the ohm's Law.	aging electrode, used electrode should not exceed ± 20% of the initial average impedance.		
Waveform &Output Test	The test sample is the final, finished product.	Use Electrical Load as load, connect to matched electrodes. Then use oscilloscope to test the output waveform (voltage, frequency) between two electrodes.	According to "IEC 60601-2-10, Particular requirements for the safety of nerve and muscle stimulators", the limitation of output parameters with 500Ω resistance load should meet the following requirement: ● The output current limit r.m.s. with 500Ω resistance load is 80mA ● For pulse durations of less than 0.1s, the pulse energy with 500Ω resistance load shall not exceed 300mJ per pulse. ● The output voltage shall not exceed a peak value of 500V, when measured under open-circuit condition.	NA	Pass

			• Otherwise, the following two Acceptance Criteria for the device according to FDA Guidance. • Maximum Power Density < 0.25 (W/cm²)		

2) Biocompatibility testing

The conductive hydrogel electrode of ManaFlexx 2 is identical to the SM Electrodes as it was cleared in K183154, 2019, in formulation, processing, and sterilization, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents. Etc.).

3) Usability Testing

Usability testing was conducted on the ManaFlexx2, the device complies with IEC 62366-1 and IEC 60601-1-6.

4) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

5) Cybersecurity

The subject device no any external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no need cybersecurity evaluation.

6) Shelf-life testing

Shelf life testing was conducted to study the adhesion, conformability of the electrode and the electrical outputs during its shelf-life, and the acceptable criteria of the shelf life testing is similar to K171722. The result show that the device can maintain it performance in 2 years.

8.2 Clinical Performance

Clinical testing was not performed on the device.

9. Final Conclusion：

The subject device ManaFlexx2 has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device K191151 and reference device K200237.