September 12, 2025

Enraf-Nonius, B.V.
℅ Scott Blood
Principal Regulatory Consultant
QARA Consulting LLC
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K251083
Trade/Device Name: Compact II
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: April 9, 2025
Received: April 9, 2025

Dear Scott Blood:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Jitendra V. Virani -S

CDR Jitendra Virani
Assistant 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251083

Device Name

Compact II

Indications for Use *(Describe)*

The Compact II is indicated for:

* Relaxation of muscle spasms;
* Prevention or retardation of disuse atrophy;
* Increasing local blood circulation;
* Muscle re-education;
* Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and
* Maintaining or increasing range of motion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Compact II
K251083

Basic Information

1. **Submitter:**

510(k) Owner:	Enraf-Nonius B.V 127, Vareseweg Rotterdam, Zuid-Holland, NL-3047AT THE NETHERLANDS
Official Correspondent:	Scott Blood Principal Consultant Phone: 978.729.5978 Fax: +49 731 9761 118 E-Mail: scottqara@gmail.com
Date Summary Prepared:	September 11, 2025

2. **Device Name:**

Trade Name:	Compact II
Classification Name:	Powered Muscle Stimulator
Regulation Number:	890.5850
Product Code:	IPF
Classification:	Class II

3. **Predicate Device:**

Device Name**:**	Talent-Pro Electromagnetic Stimulator
Company Name:	REMED K202031

4. **Device Description:**

The Compact II device generates (or induces) electric current in targeted tissues. affected by a high induction magnetic field to stimulate those tissues to treat the indicated conditions.

The device includes a transducer, which is used to provide the magnetic stimulation, which creates electrical fields by pulse current flowing from a capacitor according to the principle of Faraday's Law. Whenever the capacitor bank is discharged by the action of the control system, a pulse of current flows through the stimulating coil. The magnetic stimulation creates intense, rapidly changing magnetic electrical fields.

The Compact II device consists of a console and transducer for magnetic stimulation. The

function of magnetic stimulation is operated by adjusting parameters such as Mode, Intensity and Time. These parameters can be controlled by users on the LCD Touch Screen.

5. Indications for Use Statement:

Indications for Use	**SUBJECT DEVICE** **Enraf-Nonius B.V.** **Compact II** **K251083**	**PREDICATE DEVICE** **REMED Talent-Pro Electromagnetic Stimulator** **K202031**
Indications for Use	The Compact II is indicated for: • Relaxation of muscle spasms; • Prevention or retardation of disuse atrophy; • Increasing local blood circulation; • Muscle re-education; • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and • Maintaining or increasing range of motion.	The Talent-Pro™ Electromagnetic Stimulator is intended to be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions. The Talent-Pro™ Electromagnetic Stimulator is indicated for use in stimulating neuromuscular tissue for bulk muscle excitation in the legs or arms for rehabilitative purposes. Indications for Use for Muscle Stimulators: • Relaxation of muscle spasms; • Prevention or retardation of disuse atrophy; • Increasing local blood circulation; • Muscle re-education; • Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and • Maintaining or increasing range of motion.

The Indications for Use statement for Compact II uses much of the same Indications for Use as that of the predicate device.

6. Technological Characteristics:

Technological Characteristic	SUBJECT DEVICE Enraf-Nonius, B.V. Compact II This Submission	PREDICATE DEVICE REMED Talent-Pro Electromagnetic Stimulator K202031	Substantial Equivalence Assessment
Primary Function	Muscle stimulation	Muscle stimulation	Identical
Electrical Protection	Class I, BF	Class I, BF	Identical
User Interface	Touch Screen	Touch screen	Identical
Touch screen size	8”	8”	Identical
Type of Energy	Magnetic Field	Magnetic field	Identical
Number of Applicators	1	2	Different, See below
Number of Magnetic Coils in the Applicator	1	1	Identical
Magnetic Field Intensity	1.0 – 2.5 T	Applicator A: 1.0 – 2.5 T Applicator B: 1.0 – 2.5 T	Identical
Type of Operation	Continuous	Continuous	Identical
Pulse Repetition Rate	1 – 100 Hz (+/- 20%)	1 – 150 Hz	Different, See below
Pulse Duration	420 µs +/- 20%	280 µs +/- 20%	Different, See below
Pulse Amplitude	0 – 100%	0 – 100 %	Identical
Selection of parameters (Intensity, Time)	Yes	Yes	Identical
Therapy Time	60 minutes maximum	Up to 60 min	Identical
Shape of Stimulation Pulse	Symmetrical Biphasic Sine Wave	Symmetrical Biphasic Sine Wave	Identical
Energy Source	220-240 V~, 50-60 Hz	120V~, 60 Hz, 1500A	Different, See below
System Dimensions (WxHxD)	440 x 200 x 338 mm	542 x 501 x 1073 mm	Different, See below
Housing materials and construction	Polycarbonate	Not listed	Assumed to be identical
Operating Ambient Temperature	5° C to 28° C	10° C to 30° C	Different, See below
Operating Ambient Humidity	30 - 75% RH	30 - 85% RH	Different, See below
Weight	Approximately 23 kg	Approximately 60 kg	Different, See below

Technological Characteristic	SUBJECT DEVICE Enraf-Nonius, B.V. Compact II This Submission	PREDICATE DEVICE REMED Talent-Pro Electromagnetic Stimulator K202031	Substantial Equivalence Assessment
Position	Vertical On casters	Vertical On casters	Identical

7. Discussion Of Differences:

Technological Characteristics	Characteristic difference between Compact II and predicate device, Talent-Pro	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Number of Applicators	Compact II 1 versus Talent-Pro 2	The applicators for the Talent-Pro have the same field intensity, so their individual use is based on different performance characteristics, just physical size over the therapy area. The user can only use one applicator at a time during therapy, so there is no advantage to having two applicators versus one. The differences in intensity are discussed below.
Pulse Repetition Rate	Compact II 1 – 100 Hz (+/- 20%) versus Talent-Pro 1 – 150 Hz	The Compact II maximum pulse repetition rate is 100Hz, but it allowed to vary as much as 20% or 120 Hz. All electrical safety and product testing has been conducted at or below this maximum level. The company wishes to remind FDA that pulse repetition rate is a settable parameter by the user on both the subject and predicate devices, depending on the condition and area to be treated. This parameter is one a few that are settable by the user and performance of the device is fully under the vigilant monitoring of the user physician. The company feels that having a lower maximum pulse repetition rate setting offers a safer patient experience by not allowing for a treatment area to become inadvertently overstimulated due to exposure from a higher-than-typical pulse rate. The worst-case condition of "under" exposure is that the user would need to decide whether more treatment time at the same exposure rate would be needed.. This difference does not create any new additional questions of device performance when compared to the predicate device.
Pulse Duration	Compact II 420 µs +/- 20% versus Talent-Pro 280 +/- 20% µs	The pulse width of the Compact II device and the predicate device are in the typical clinical range of 50 to 500µs, so this difference does not create any new additional questions of device performance when compared to the predicate device. Reference: "the effect of stimulus current pulse width on nerve fiber size recruitment patterns" by Robert B. Szlavik and Hubert de Bruin
Energy Source	Compact II 220-240 V~, 50-60 Hz versus Talent-Pro 120V~, 60 Hz, 1500A	Both the subject device and the predicate device have been tested for safety to US power requirements with their respective power entry systems per IEC 60601-1.

Technological Characteristics	Characteristic difference between Compact II and predicate device, Talent-Pro	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
System Dimensions (WxHxD)	Compact II 440 x 200 x 338 mm versus Talent-Pro 542x501x993 mm	Different device form factors have no influence on the safety or effectiveness of the device. The usability is passed successfully.
Operating Ambient Temperature and Humidity	Compact II 5° C to 28° C 30 – 75% versus Talent-Pro 10° C to 30° C 30-85%	Both the subject device and the predicate device are well within the use ranges that are expected of office-based medical devices. The differences here are not important for the device safety and effectiveness evaluation.
Weight	23kg versus 60kg	Both the subject device and the predicate device are well within the physical size expected of office-based medical devices. The difference here are not important for the device safety and effectiveness evaluation

In summary, most of the technological characteristics of the subject device and the predicate device are exactly the same. Those differences in characteristics that do exist are still similar enough to allow for considering the two devices substantially equivalent.

8. Summary of Non-clinical Testing:

The technological characteristics of the Compact II device has been verified based on assessments of electrical safety, performance, biocompatibility, software and usability.

The device has been found to comply with applicable medical device safety standards:

IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic Disturbance – Requirements and tests

IEC TS 60601-4-2 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

IEC 62304 Medical device software – Software life cycle processes

ISO 14971 Medical devices – Application of risk management to medical devices

ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro

cytotoxicity

ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

IEC 62366 Medical devices – Application of usability engineering to medical devices

The following testing has been conducted with satisfactory results:

- Electromagnetic compatibility: EMC testing was done to evaluate emissions and immunity to electromagnetic fields in accordance with IEC 60601-1-2 and IEC 60601-4-2.
- Electrical and mechanical safety: Full electrical safety testing was done in compliance with IEC 60601-1.
- Biocompatibility: Biocompatibility of the patient- and user-contacting parts of the transducers were tested per ISO 10993-1 and its corollaries.
- Transducer performance, such as magnetic field strength, field spatial distribution, and magnetic field strength gradient were tested using calibrated instruments.

Testing has been performed on final, finished devices and these systems have met the required specifications for the completed tests.

9. Conclusion:

The Indications for Use for the Compact II uses much of the same language as that of the predicate device and many of the technological characteristics between the Compact II and the predicate device are the same. The minor differences mentioned above do not raise new questions of safety or effectiveness. The Compact II may be considered substantially equivalent as the predicate device.