October 24, 2023

Enraf-Nonius, B.V.
℅ Scott Blood
Regulatory Consultant
Quality and Regulatory Services
151 Gleasondale Road
Stow, Massachusetts 01775

Re: K230472
Trade/Device Name: Sonopuls 190
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI
Dated: September 20, 2023
Received: September 22, 2023

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.

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
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)*
K230472

Device Name
Sonopuls 190

Indications for Use *(Describe)*
Therapeutic Ultrasound is indicated for:
* Pain Relief
* Reduction of muscle spasms
* Localized increase in blood flow
* Increase range of motion of contracted joints using heat and stretch techniques

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

Sonopuls 190

K230472

1. **Basic Information-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:	October 23, 2023

2. **Device Name:**

Trade Name:	Sonopuls 190
Classification Name:	Ultrasonic Diathermy for Use in Applying Therapeutic Deep Heat
Regulation Number:	890.5300
Product Code:	IMI
Classification:	Class II

3. **Predicate Device:** Sonomed IV/Sonomed V

Company Name:	Carci Industria E Comercio De Aparelhos Cirurgicos E Orto
	K202788

4. **Reference Device**: Omniversa Multi-Modality Therapy System Accelerated Care Plus (ACP)
K153559

5. **Device Description**:

This device is a multi-frequency ultrasound therapy equipment. The mounted applicators provide both 1 and 3 MHz operation. Depending on the area of treatment, two different types of applicators, large and small, are available. They are suitable for treatment under water.

Contact control suspends the application of ultrasound energy when acoustical contact with the treatment area becomes insufficient. The user can connect two ultrasound applicators. Activation of each applicator can be controlled from the ultrasound menu.

This device is a prescription equipment. Use by any persons other than physicians is prohibited.

6. **Indications for Use Statement**:

Regulatory Characteristics	Subject Device Enraf-Nonius B.V. Sonopuls 190 This Submission	Predicate Device CARCI Indústria Sonomed IV/V K202788	Substantial Equivalence Comments (Subject vs Predicate)
Indications for Use	Therapeutic Ultrasound is indicated for: • Pain Relief • Reduction of muscle spasms • Localized increase in blood flow • Increase range of motion of contracted joints using heat and stretch techniques	Therapeutic Ultrasound • Pain Relief • Reduction of muscle spasms • Localized increase in blood flow • Increase range of motion of contracted joints using heat and stretch techniques	Similar
Product Code & Regulation	IMI, 890.5300	IMI, 890.5300	Identical

7. **Technological Characteristics**:

Both the subject device and predicate device use the same ultrasound frequencies (1 MHz, 3 MHz) to meet their Indications for Use. The devices are technologically equivalent, however the specific predicate device parameters have not been published in the publicly-available 510(k) statement.

Technological Characteristics	Subject Device Enraf-Nonius B.V. Sonopuls 190 This Submission	Predicate Device CARCI Indústria Sonomed IV/V K202788	Substantial Equivalence Comments (Subject vs Predicate)
Patient Leakage Current	1 µA typical (requirements IEC < 10 µA)	Not publicly available	Not Available
Crystal Material	PZT-8 (lead zirconate titanate) piezoceramic material	PZT	Similar

Technological Characteristics	Subject Device Enraf-Nonius B.V. Sonopuls 190 This Submission	Predicate Device CARCI Indústria Sonomed IV/V K202788	Substantial Equivalence Comments (Subject vs Predicate)
Technology of ultrasound generation (e.g., piezoelectric, magnetostrictive)	piezoelectric	piezoelectric	Identical
Power source	100 – 240 VAC +/- 10%	100 – 240 VAC	Similar
Method of Line Current Isolation	Transformer & Opto Isolated	Not Publicly Available	Not available
Output Mode	Continuous Pulsed	Continuous Pulsed	Identical
Beam Type (collimated or divergent)	5 cm^2 applicator: 1 MHz: collimating 3 MHz: collimating 0.8 cm^2 applicator: 1 MHz: collimating 3 MHz: diverging	Collimated	Similar
Intensity	0 – 3.0 W/cm^2	0.1 – 2.0 W/cm^2 (cont) 0.1 – 3.0 W/cm^2 (pulsed)	Similar
Frequency	1 MHz 3 MHz	1 MHz +/-5% 3 MHz +/-5%	Similar
Acoustic Working Frequency and Accuracy (MHz)	5 cm^2, 0.8 cm^2 and 1 MHz: 0.98 MHz ± 5% 3 MHz: 3.1 MHz ± 5%	1 MHz ± 5% 3.3 MHz ± 5%	Similar
Effective Radiating Area and Accuracy	5 cm^2 applicator: 5 cm^2 ± 20% 0.8 cm^2 applicator: 0.8 cm^2 ± 20%	3.2cm^2 +/- 10%	Different
Beam Nonuniformity Ratio and Accuracy	6:1 maximum	2.8:1 maximum	Different
Pulse Frequency	16Hz, 48Hz, 100Hz +/-1%	Not publicly available	Not available

Technological Characteristics	Subject Device Enraf-Nonius B.V. Sonopuls 190 This Submission	Predicate Device CARCI Indústria Sonomed IV/V K202788	Substantial Equivalence Comments (Subject vs Predicate)
Temporal Max Power (W) – [for pulsed]	5 cm2 applicator: duty cycle 5-50%: 15W duty cycle 80%: 12W 0.8 cm2 applicator: duty cycle 5-50% 2.4 W duty cycle 80%: 2 W	Not publicly available	Not available
Temporal Max Power (W) – [for continuous]	5 cm2 applicator: 10 W 0.8 cm2 applicator: 1.6 W	Not publicly available	Not available
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	5 cm^2 applicator: 10 W ± 20% 0.8 cm^2 applicator: 2 W ± 20%	6.4 W ± 20%	Different
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	Elevation of temperature raise 4.8ºC for 10 minutes 1.0MHz, 2.0W Effective depth 2.5cm Elevation of temperature raise 5.8ºC for 3 minutes 3.0MHz, 2.0W Effective depth 0.8cm	Head in the air Elevation of temperature raise 18ºC for 20 minutes 1MHz, 6.4W Elevation of temperature raise 19ºC for 20 minutes 3.3MHz, 6.4W Effective depth 3cm for 1MHz and 1cm for 3MHz	Different

Technological Characteristics	Subject Device Enraf-Nonius B.V. Sonopuls 190 This Submission	Predicate Device CARCI Indústria Sonomed IV/V K202788	Substantial Equivalence Comments (Subject vs Predicate)
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated fixed Treatment Head Placement) (deg C) or Actual Use Conditions for all Operating Conditions (Continually operated for maximum treatment time) (deg C)	5 cm2 applicator <43 deg C 0.8 cm2 applicator <34 deg C	Head in the MMT 32 ºC for 1MHz continuous use 6.4W 36 ºC for 3.3MHz continuous use 6.4W	Different
Penetration Depth	1Mhz 2.5cm 3.0MHz 0.8cm	1Mhz 5cm 3.3MHz 2cm	Different
Ultrasound Heads	0.8 cm^2 5 cm^2	5 cm^2	Similar
# of Output Modes	2	2	Identical
Timer Range (minutes)	0 - 10	0 - 20	Similar
Compliance to Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-5 IEC 62304 ISO 10993-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-5	Similar
Weight (Console & Treatment head)	7 lbs 2oz	3 lbs 3 oz	Different
Dimensions (W x H x D)	6.25“ x 5.5“ x 8“	12.2“ x 2.3“ x 7“	Different
Housing Materials and Construction	ABS	Not Publicly Available	Not available

8. Discussion of Differences

Technological Characteristics	Characteristic differences between Sonopuls 190 and predicate device	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Effective Radiating Area and Accuracy	The subject device has an ERA of 5cm^2±20% and the predicate device has an ERA of 3.2cm^2±10% with the same size (5cm^2 applicator	The Effective Radiating Area (ERA) of the transducer of the same area as the transducer head for the subject device, and a fraction of the predicate device transducer's area, which is more typical for ultrasound transducers. The accuracy is superior with the predicate device transducer. There are no new questions of safety or performance because the ERA is identical to the Omniversa device (the reference device) which has been cleared as an ultrasound diathermy physical therapeutic device using the same ERA parameters as the subject device.
Beam Nonuniformity Ratio and Accuracy	6.1 maximum versus 2.8:1 maximum	Although different between the subject and predicate devices, the differences in Beam Nonuniformity Ratio (BNR) are somewhat similar as compared to values in other cleared ultrasound diathermy devices, which can range between 2 and 6:1. There are no new questions of safety or performance because the ERA is identical to the Omniversa device (the reference device) which has been cleared as an ultrasound diathermy physical therapeutic device using the same ERA parameters as the subject device.
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	5 cm^2 applicator: 10 W ± 20% and 0.8 cm^2 applicator: 2 W ± 20% versus 6.4 W ± 20%	Although the maximum output power mean values are different between the subject and predicate devices, the reference device of the subject device was used safely in thermal tissue testing to support this submission.
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	In summary, the peak temperature rise and tissue depth for the subject device is less over a shorter treatment time than that of the predicate device.	Although the peak temperature rise over treatment time and tissue depth is less for the subject device when compared to the predicate device, there are no new questions of safety as the lower temperature rise over time and tissue depth is lower and slower, and thus safer for the patient.
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated fixed Treatment Head Placement) (deg C) or Actual Use Conditions for all Operating Conditions (Continually operated for maximum treatment time) (deg C)	In summary, the subject device maintained a maximum temperature of under 43°C at the maximum output setting where the predicate device maximum temperature operated under 36°C.	The subject device operation resulted in a maximum patient contact temperature of under 43°C. The reference device of the subject device was used safely in thermal tissue testing to support this submission.

Technological Characteristics	Characteristic differences between Sonopuls 190 and predicate device	Discussion on why this difference does not affect the overall safety and effectiveness of the subject device when compared to the predicate device
Penetration depth	1MHz - 2.5cm 3.0MHz - 0.8cm Versus 1MHz - 5cm 3.3MHz - 2cm	The subject device appears to have less penetration depth than the predicate. From a safety standpoint, less penetration is safer for the user. Device performance was established in the thermal tissue test study that support this submission.
Timer Range (Treatment Time)	10 minutes maximum versus 20 minutes maximum	The maximum allowable treatment time is half of what the predicate device allows. Because the exposure of energy during the treatment is less than the predicate, there are no new questions of safety with this difference. Device performance was established in the thermal tissue test study performed using the reference device of the subject device to support this submission, so there are no new question of device performance.
Weight and Dimensions	7lbs 2 oz, 6.25“ x 5.5“ x 8“ versus 3 lbs 3oz, 12.2“ x 2.3“ x 7“	Different weights and dimensions have no influence on the safety or effectiveness of the device..

9. **Summary of Testing**:

The technological characteristics of the Sonopuls 190 device has been verified based on assessments of electrical safety, performance, biocompatibility, and software.

The following testing has been conducted with satisfactory results:

- Biocompatibility: ISO 10993-1:2018 (Edition 5) *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process:* Samples of the user and patient-contacting were tested for biocompatibility.
- Software Assessment: IEC 62304:2015 *Medical devices software –software life cycle processes:* Software features were assessed in accordance with FDA software validation guidelines. Levels of Concern, User & System Requirements, Hazard Analysis, Software Requirements, Architectural Design, Software Validation & Testing were all addressed.
- Electromagnetic compatibility: IEC 60601-1-2:2014 *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*: EMC testing was done to evaluate emissions and immunity to electromagnetic fields.
- Electrical safety: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*: Full electrical safety testing was completed.
- Ultrasonic physiotherapy equipment: IEC 60601-2-5 Edition 3.0 2009-07 *Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and*

essential performance of ultrasonic physiotherapy equipment: Ultrasonic physiotherapy equipment requirements were tested.

The Sonopuls 190 device has been assessed and/or tested for compliance to the following voluntary standards:

Standards	**SUBJECT DEVICE Enraf-Nonius B.V. Sonopuls 190 K230472**	**Predicate Device CARCI Indústria Sonomed IV/V K202788**
ANSI AAMI ES60601-1	X	X
IEC 60601-1-2	X	X
IEC 60601-2-5	X	X
IEC 62304	X	X
ISO 10993-1	X	X

All required performance tests were conducted and show substantial equivalence with the predicate device. Sonopuls 190 has been designed and tested to more contemporary standards, as well as additional standards that are used to support the subject device 510(k) submission. Testing has been performed on final, finished devices and these systems have met the required specifications for the completed tests.

10. **Conclusion**:

Enraf-Nonius B.V has demonstrated that the Sonopuls 190 device is substantially equivalent to the predicate device.