June 25, 2025

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

Re: K243112
Trade/Device Name: Curapuls 670
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: September 30, 2024
Received: September 30, 2024

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,

Lauren E. Woodard -S

for Amber Ballard, PhD
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)*

K243112

Device Name

Curapuls 670

Indications for Use *(Describe)*

The Curapuls 670 is indicated to be used for applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as:
1. Relieving pain;
2. Reducing muscle spasm;
3. Increasing range of motion of contracted joints using heat and stretch techniques; and
4. Increasing blood flow to tissues in the treatment area.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Curapuls 670

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: scottgara@gmail.com

Date Summary Prepared: May 27, 2025

2. Device Name:

Trade Name: Curapuls 670
Classification Name: Diathermy, Shortwave, For the Use in Applying Therapeutic Deep Heat
Regulation Number: 890.5290
Product Code: IMJ
Classification: Class II

3. **Predicate Device:** BTL-703
Company Name: BTL Industries, Inc.
K182363

4. **Device Description**:

The Curapuls 670 is a two-channel microprocessor-controlled unit for pulsed shortwave therapy. Through inductive electrodes (Circuplodes), high-frequency electric currents are produced within the body. Pulsed energy at 27.12 MHz is absorbed by soft tissues. Three sizes of Circuplodes (140mm, 90mm and elliptical) are available to accommodate different size treatment areas.

Deep heating of tissue is achieved with ease by means of inductive electrodes. The user can connect two applicators. Activation of each applicator can be controlled from the console menu.

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

5. **Indications for Use Statement**:

Indications for Use	SUBJECT DEVICE Enraf-Nonius B.V. Curapuls 670 This Submission	PREDICATE DEVICE BTL Industries, Inc. BTL-703 K182363
Indications for Use	Used for applying therapeutic deep heat in body tissues in adults for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.	Used for applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing range of motion of contracted joints using heat and stretch techniques; and 4. Increasing blood flow to tissues in the treatment area.

The Indications for Use statement for Curapuls 670 is similar to the predicate device.

6. **Technological Characteristics**:

Both the subject device and predicate device use the same frequency (27.12 MHz) to meet their Indications for Use. The devices are mostly technologically equivalent. The minor differences shown below do not raise new questions of safety or effectiveness.

Technological Characteristics	SUBJECT DEVICE Enraf-Nonius B.V. Curapuls 670 This Submission	PREDICATE DEVICE BTL Industries, Inc. BTL-703 K182363	Substantial Equivalence Comments
Working Frequency	27.12 MHz	27.12 MHz	Identical
Power source	100 – 240 VAC +/- 10%	Internal, 120 VAC	Different
Peak Output Power	200 W	2 x 100 W (Continuous)	Similar
Pulse Width	65 – 400 µs	Not publicly available	--------
Pulse Frequency	26 – 800 Hz	Not publicly available	-------
Mean Power	0 – 64 W	Not publicly available	-------
Electrical Protection	Class II, BF	Class II, BF	Identical
User Interface	Touchscreen	Touchscreen	Identical
Firmware Controlled	Yes	Yes	Identical

Technological Characteristics	SUBJECT DEVICE Enraf-Nonius B.V. Curapuls 670 This Submission	PREDICATE DEVICE BTL Industries, Inc. BTL-703 K182363	Substantial Equivalence Comments
Energy Type	High-frequency electromagnetic current	High-frequency electromagnetic current	Identical
Mode of Operation	Pulsed	Continuous	Different
Applicator type	Capacitive	Capacitive	Identical
Applicator size	90 mm diameter 140 mm diameter Oval	100mm diameter	Similar
Indicator Display On/Off Status? Low Battery? Voltage/Current level?	Yes Yes Yes	Yes Yes Yes	Identical
Way of Applicator Attachment	Mechanical	Negative Pressure	Different
Applicator sleeves	No	Yes	Different
Thermal Stabilization System	No	Yes	Different
Arm Control	Mechanical	Electrical / Mechanical	Similar
Hands-Free Application	Yes	Yes	Identical
Stop Remote Control	Yes	Yes	Identical
Applicator Contact Monitor	No	Yes	Different
Timer Range (minutes)	0 – 30 min	0 – 30 min	Identical
Compliance to Standards	IEC 60601-1 IEC 60601-1-2 IEC 62304 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 62304 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10	Identical
Weight	60 lbs	Not publicaly available	Unknown
Dimensions (W x H x D)	22.0“ x 43.3“ x 18.9“	24.7“ x 38.8“ x 26.5“	Different

Technological Characteristics	SUBJECT DEVICE Enraf-Nonius B.V. Curapuls 670 This Submission	PREDICATE DEVICE BTL Industries, Inc. BTL-703 K182363	Substantial Equivalence Comments
Housing Materials and Construction	Aluminum, polycarbonate-ABS, polycarbonate, ABS, glass, polyethlyene, POM	Not publicly available	-------

Discussion of Differences

Indications for use are identical for both subject and predicate devices.

Technological Characteristics	Characteristic differences between Curapuls 670 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
Mode of Operation	Pulsed versus Continuous	Both pulses and continuous modes of shortwave diathermy are used in already-cleared medical devices. While continuous mode does allow for faster temperature rise in tissue, both modes have been tested for thermal effect in tissue as part of device clearance.
Way of Application Attachment	Mechanical versus Negative Pressure	The predicate device uses negative pressure to hold the applicator in place on the patient's skin. The silicone applicator sleeves, thermal stabilization system, and applicator contact monitor are all part of that negative pressure system. The subject device uses a mechanical arm system to hold the applicator in position. The negative pressure applicator accessories are not needed when mechanical means of applicator attachment are employed.
Applicator sleeves	None versus Yes	
Thermal Stabilization System	None versus Yes	
Applicator Contact Monitor	None versus Yes	
Power Source	100 – 240 VAC +/- 10% versus 120 VAC	Subject device has been tested for electrical safety per IEC 60601-1. The power source does not create any new questions of safety and effectiveness.
Dimensions	22.0" x 43.3" x 18.9" versus 24.7" x 38.8" x 26.5"	Different form factor has no influence on the safety or effectiveness of the device.

7. **Summary of Non-clinical Testing**:

The technological characteristics of the Curapuls 670 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 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

The following testing has been conducted with satisfactory results:

- Usability: Usability assessments were done to verify user interface, safety features and satisfactory performance.
- Electromagnetic compatibility: EMC testing was done to evaluate emissions and immunity to electromagnetic fields in accordance with IEC 60601-1-2.
- Electrical and mechanical safety: Full electrical safety testing was done in compliance with ANSI AAMI ES60601-1.
- Thermal effect on tissue: Demonstrated the device is able to maintain temperature in the range of approximately 40-45°C in vivo.

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

8. **Conclusion**:

There are no differences with respect to the indications for use and many of the technological characteristics between the Curapuls 670 and the predicate device. The minor differences mentioned above do not raise new questions of safety or effectiveness.