June 15, 2026

Tournicare Pty Ltd.
Roger Gray
VP Qa/ra
Donawa Lifescience
Piazza Albania 10
Rome, 00153
Italy

Re: K253059
Trade/Device Name: Tournicare ARMA Automatic Blood Pressure Monitor (ARMA-08)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2026
Received: May 15, 2026

Dear Roger Gray:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253059

Please provide the device trade name(s).

Tournicare ARMA Automatic Blood Pressure Monitor (ARMA-08)

Please provide your Indications for Use below.

The ARMA automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is clamped to the upper arm. The intended upper arm circumference is 24 cm to 36 cm (9.4 in to 14.2 in).

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K253059

510(k) Summary

Prepared on: 2026-06-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tournicare Pty Ltd.
Applicant Address	18 Elliot Avenue Balwyn Victoria 3103 Australia
Applicant Contact Telephone	+61 (0) 414 373
Applicant Contact	Mr. Niels van Sparrentak
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Correspondent Name	Donawa Lifescience
Correspondent Address	Piazza Albania 10 Rome 00153 Italy
Correspondent Contact Telephone	+39 06 578 2665
Correspondent Contact	Mr. Roger Gray
Correspondent Contact Email	rgray@donawa.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tournicare ARMA Automatic Blood Pressure Monitor (ARMA-08)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162092	Omron Evolv Model BP7000 Upper Arm Blood Pressure Monitor	DXN

Device Description Summary

21 CFR 807.92(a)(4)

The ARMA Blood Pressure Monitor (BPM) device is an automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate. The device is powered by a rechargeable battery and is designed for home (OTC) use. ARMA BPM operates by occluding the brachial artery with an inflatable bladder. A pressure sensor detects and generates an oscillometric waveform from which systolic and diastolic blood pressure values and the pulse rate are extrapolated. The physical architecture of the device is different from classic blood pressure measurement cuffs which feature a full wrap-around cuff and bladder, whereas the ARMA uses a clamp mechanism and bladder. A size insert is also supplied with the device for users with a small arm circumference 24 cm to 26 cm.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ARMA automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood

pressures and pulse rate of adults by means of an inflatable cuff which is clamped to the upper arm. The intended upper arm circumference is 24 cm to 36 cm (9.4 in to 14.2 in).

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications for use are substantially similar. The subject device does not include irregular heartbeat detection, which is included in the predicate device. The upper arm circumference range is different, with the subject device having a smaller arm circumference range. These differences do not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices are both battery-powered and use the same principle of operation (oscillometric method, automatic inflation, deflation and measurement) to measure the user's blood pressure and pulse rate.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing included demonstration of compliance with applicable international, FDA-recognized, standards including:

Electrical safety in accordance with IEC 60601-1 and IEC 80601-2-30
EMC (Electromagnetic Compatibility) in accordance with IEC 60601-1-2
Lithium-ion battery safety in accordance with IEC 62133-2
Software life cycle compliance in accordance with IEC 62304
Human factors in accordance with ISO/IEC 62366-1
Transportation simulation in accordance with ISTA 3A
Biocompatibility of patient-contacting parts in accordance with FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff", September 8, 2023

Clinical testing was carried out in accordance with international, FDA-recognized, standard ISO 81060-2:2018, "Non-invasive sphygmomanometers, Part 2: Clinical investigation of intermittent automated measurement type", to evaluate the accuracy of the ARMA device.

ARMA BPM has similar indications for use, technological characteristics, and principles of operation to the predicate device cleared under 510(k) submission K162092. Clinical and bench test performance data demonstrate that the ARMA BPM is as safe and as effective as the predicate and does not raise any new safety and effectiveness concerns. Clinical performance has been validated in accordance with an FDA-recognized standard.