April 12, 2023

CNSystems Medizintechnik GmbH
Raphael Gunacker
Head of Quality
Reininghausstrasse 13
Graz, 8020
Austria

Re: K223332
Trade/Device Name: Task Force CORE
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN,
Dated: October 21, 2022
Received: October 31, 2022

Dear Raphael Gunacker:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 T. Kazmierski -S

for

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

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)*
K223332

Device Name
Task Force® CORE

Indications for Use *(Describe)*

The Task Force® CORE (TFC) is intended for the measurement of non-invasive continuous blood pressure, pulse rate, and the determination of associated derived hemodynamic parameters.

The TFC is intended to be used in professional healthcare facilities and operated by qualified healthcare professional staff. The TFC is intended to be used for adults and under uninterrupted surveillance of the operator.

The TFC contains software which runs on a separate computer and which is used to operate the device. This software includes a basic frontend (Task Force® CORE Viewer) as well as an interface for integration into other software products.

The TFC can provide all signals as well as measured and derived parameters to the analog output interface and can acquire signals from the analog input interface.

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."

5 510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

5.1 Submitter's Information

510(k) submitter	CNSystems Medizintechnik GmbH Reininghausstrasse 13 8020 Graz, Austria Tel: 0043-316-723456-0 e-Mail: regulatory@cnsystems.com Establishment Registration Number: 3006113127
Primary contact person	Raphael Gunacker/ Head of Quality Tel: 0043-316-723456-701 E-Mail: raphael.gunacker@cnsystems.com
Alternate contact person	Tijana Rajcevic/ Regulatory Affairs & Quality Manager Tel: 0043-316-723456-703 E-Mail: tijana.rajcevic@cnsystems.com
Date prepared	March 6th , 2023

5.2 Device Information

Trade/Device name	Task Force® CORE
Common name	Measurement system for continuous non-invasive blood pressure, pulse rate and hemodynamics
Regulation number	21 CFR 870.1130
Regulation name	Noninvasive blood pressure measurement system
Regulatory class	Class II
Product code	DXN
Review panel	Cardiovascular devices

5.4 Predicate Devices

5.4.1 Primary predicate device (PPD): Finapres NOVA: K173916

Manufacturer: Finapres Medical Systems B.V.
Hogehilweg 8, 1101 CC Amsterdam, The Netherlands

The Finapres NOVA is a medical device for continuous and non-invasive blood pressure measurement and further hemodynamic parameters derived from the measured signals. The Task Force® CORE and the Finapres NOVA share the same intended use and the same fields of application in the market.

5.4.2 Secondary predicate device (SPD): CNAP® Monitor 500 HD: K183521

Manufacturer: CNSystems Medizintechnik GmbH
Graz, Austria

The CNAP® Monitor 500HD is a stand-alone device for continuous non-invasive blood pressure and hemodynamic monitoring with alarming functionality. The continuous non-invasive blood pressure is measured on the patient's finger using a double finger cuff. The oscillometric blood pressure measurement function is used for intermittent calibration of the continuous blood pressure curve.

The Task Force® CORE and the CNAP® Monitor 500 HD utilize the same measurement (CNAP®) technology and share functionality and sensors, with exception for alarming functionality (according to IEC 60601-1-8) of the CNAP Monitor 500HD, which the Task Force CORE does not have.

5.5 Device Description

The medical device Task Force® CORE (TFC) with software version 1.0.7 is a new product, which is intended to be used in professional healthcare facilities and operated only by qualified healthcare professional staff, as described in the Indications for use.

The Task Force® CORE is intended to be used for the non-invasive continuous measurement of blood pressure and pulse rate, and the determination of associated derived hemodynamic parameters. . The principle of a continuous non-invasive measurement of a blood pressure is based on the Pénaz-Principle (vascular unloading).

The TFC consists of several components necessary for the intended operation:

- Task Force® CORE Main Unit -TFC MU (see Figure 1) connected to an application computer via USB.
- Applied parts (detachable components): CNAP® Classic Sensor Unit (see Figure 2) and TFC NBP Cuffs (see Figure 3)
- The TFC I/O Cable for using the Analog I/O interface (see Figure 4)

- Task Force® CORE Viewer as graphical user interface (see Figure 5) and TFC Driver, executed on an application computer (third - party manufacturer). Please note that the application computer is not a part of the subject device (SD) and therefore not within the scope of this submission.

Figure 1: Task Force Core® Main Unit

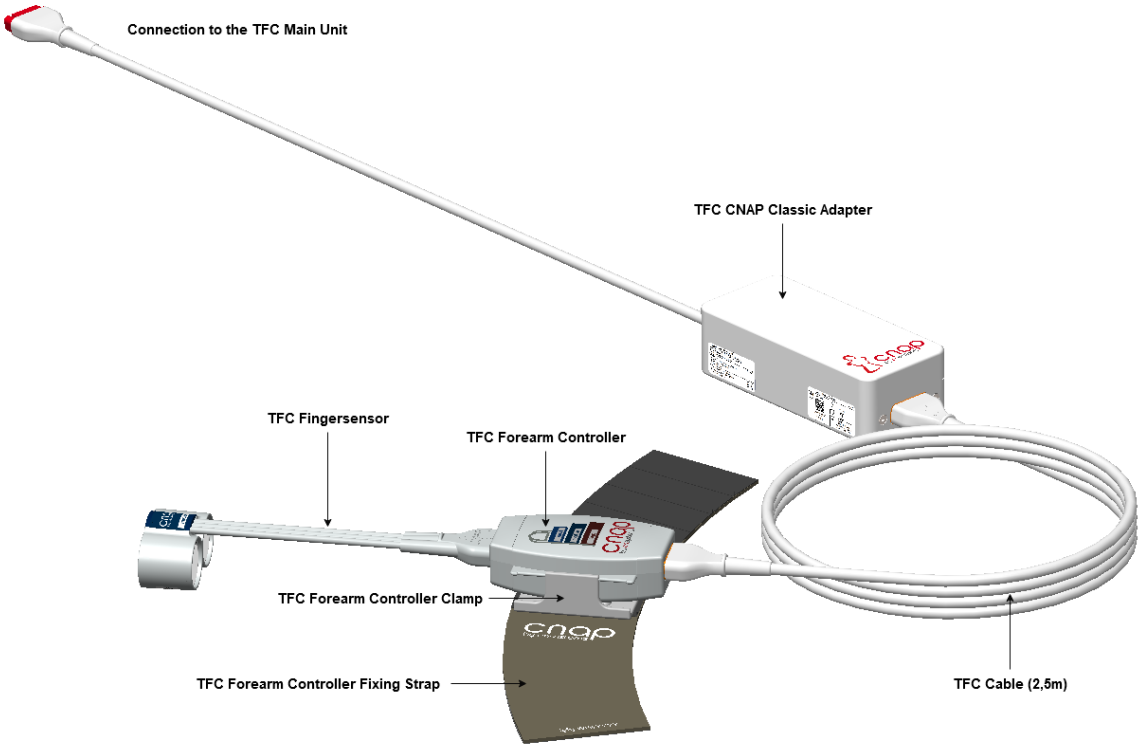

Figure 2: Components and setup of the CNAP® Classic Sensor Unit

Figure 3: TFC NBP Cuffs

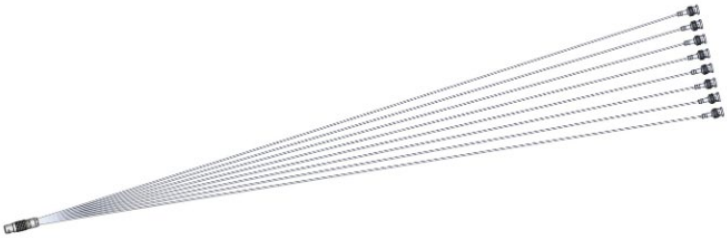

Figure 4: TFC I/O Cable

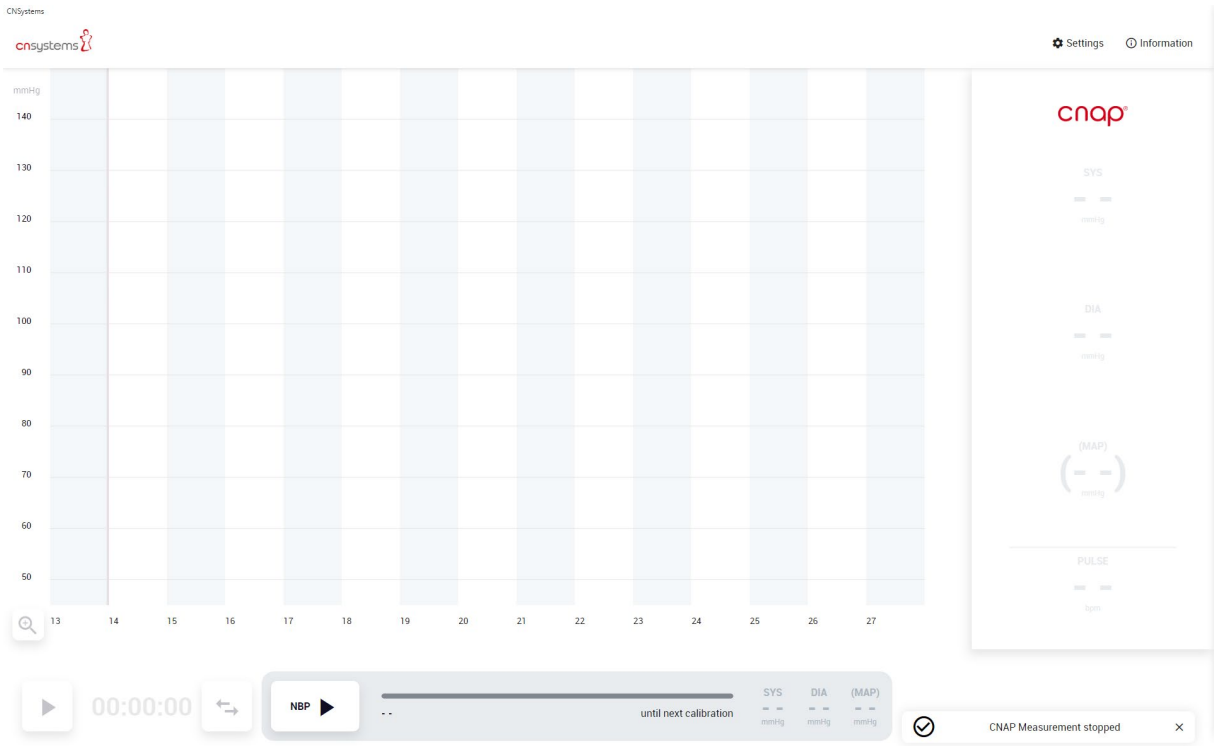

Figure 5: Task Force® CORE Viewer

Detailed description of the device is to be found in Volume 10 (Device Description).

5.5.1 TFC Touchable Components

The TFC components, which are deemed to be in direct contact with patient during measurements, are defined as the touchable components (TFC Fingersensor, TFC Forearm Controller Fixing Strap, TFC NBP Cuff and TFC Armsling). These components are intended to be in contact only with intact skin surfaces for a cumulative sum of duration of contact up to 24h.

The full description of the touchable components and the materials they are made of is included in Volume 15 (Biocompatibility).

5.6 Indications for Use

The Task Force® CORE (TFC) is intended for the measurement of non-invasive continuous blood pressure, pulse rate, and the determination of associated derived hemodynamic parameters.

The TFC is intended to be used in professional healthcare facilities and operated by qualified healthcare professional staff. The TFC is intended to be used for adults and under uninterrupted surveillance of the operator.

The TFC contains software which runs on a separate computer and which is used to operate the device. This software includes a basic frontend (Task Force® CORE Viewer) as well as an interface for integration into other software products. The TFC can provide all signals, as well as measured and derived parameters, to the analog output interface and can acquire signals from the analog input interface.

5.7 Comparison of technological characteristics with the predicate device

The SD (Task Force® CORE), as well as the PPD (Finapres NOVA) and the SPD (CNAP® Monitor 500 HD) provide a continuous non-invasive blood pressure measurement based on the Pénaz-Principle (vascular unloading), and therefore calculate the patients' blood pressure continuously via an opto-pneumatic sensor, which is applied to a patient's finger.

The Task Force® CORE and the CNAP® Monitor 500 HD utilize the same CNAP® technology and share functionality and sensors, with exception for alarming functionality (according to IEC 60601-1-8) of the CNAP Monitor 500HD, which the Task Force CORE does not have..

While both predicate devices have integrated displays, the Task Force® CORE uses an external (third-party manufacturer) application computer.

Another technological difference is the fact that the PPD relies on a height correction unit to account for hydrostatic pressure differences occurring due to movements of the finger sensor relative to the heart. On the other hand, the SD (TFC) and the SPD (CNAP® Monitor 500 HD) use algorithms for artifact detection (including movements of the sensor relative to the heart) and warnings and instructions (to recalibrate) in the instructions for use.

The present technological differences do not raise questions of safety and effectiveness.

For more details on comparison of technological characteristics between the Task Force® CORE and predicate devices, please refer to Volume 12 (Substantial equivalence discussion) of this submission.

5.8 Performance data

5.8.1 System testing

All system verification tests based on system requirements were passed, demonstrating conformance with design and performance specifications.

5.8.2 Biocompatibility testing

Biocompatibility evaluation was performed according to FDA´s guideline "Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", dated September 4th 2020 and ISO 10993-1:2018.

The Task Force® CORE is intended to contact intact skin on the upper arms and fingers of a patient, for a limited contact duration of up to 24 hours with touchable TFC components (TFC Fingersensor, TFC Forearm Controller Fixing Strap, TFC Armsling, and TFC NBP cuffs). All materials in patient contact of the Task Force® CORE are evaluated to be safe for the intended contact with intact skin and for a limited time. For more information, please refer to Volume 15 (Biocompatibility).

5.8.3 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety of the Task Force® CORE was demonstrated by type testing according to IEC 60601-1 Edition 3.1 2012 in combination with IEC 80601-2-30: Edition 2.0 2018-03.

Electromagnetic compatibly of the Task Force® CORE was demonstrated by system testing according to IEC 60601-1-2 Edition 4.0 2014-02, considering exception of recognition on subclause 8.9.

All tests on electrical safety and electromagnetic compatibility were passed. The respective test reports are attached in Volume 17 (Electromagnetic Compatibility and Electrical Safety).

5.8.4 Software verification and validation testing

For the Task Force® CORE, according to its software safety classification as B (Moderate Concern) according to IEC 62304 Edition 1.1 2015-06, all required software lifecycle activities were conducted, including system and unit level verification. Volume 16 contains the proposed content as per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Fulfillment of IEC 62304 Edition 1.1 2015-06 is also demonstrated by type testing, performed according to IEC 60601-1 Edition 3.1 2012 and IEC 62304 Edition 1.1 2015-06.

5.8.5 Clinical performance testing

For the Task Force® CORE, performance tests were conducted regarding blood pressure, cardiac output and the parameters inter-beat-interval and pulse rate.

- Clinical performance studies for blood pressure measurements included 42 (22 male, 20 female) adult subjects (age span 21 to 77 years),
- Clinical studies for cardiac output determination included 44 (37 male, 7 female) adult subjects (age span 54 to 83 years),
- The first clinical study for determination of the pulse rate and inter-beat-interval included 44 (22 male, 22 female) adult subjects (age span 21 to 77 years).
- The second clinical study for determination of the pulse rate and inter-beat-interval included 28 (16 male, 12 female) adult subjects (age span 18 to 66 years).

The patient population of the clinical performance study is representative of the intended patient population. As mentioned in the indications for use (please refer to Volume 04 Indications for Use Statement), the device is not intended to be used on pediatric patients.

Performance of blood pressure measurement was tested against the gold standard invasive arterial reference and was found to comply with the requirements of ISO 81060-2:2018.

Performance of cardiac output determination was tested against the gold standard thermodilution reference and was found to fulfill the widely accepted Critchley criteria.

Performance of the inter-beat-interval and pulse rate determinations was tested against the gold standard reference electrocardiography and was found to fulfill the requirements derived from IEC 60601-2-25:2011 and ANSI/AAMI EC13:2002, respectively.

When used according to the instructions for use, the Task Force® CORE showed no adverse effects during the clinical performance testing.

The results obtained from clinical performance testing demonstrate that the Task Force® CORE with SW V1.0.7 and HW V1.0 is substantially equivalent concerning measurement performance to the primary predicate device Finapres NOVA (K173916) and the secondary predicate device CNAP Monitor 500 HD (K183521).

5.9 Conclusion

The subject device and the two predicate devices share the same intended use and similar technological characteristics. Thus, the subject device is regarded to be substantially equivalent to the legally marketed predicates.

The Task Force® CORE successfully passed safety, functional and performance testing, including software verification and validation and bench tests.

The information submitted within the premarket notification confirms that the Task Force® CORE is as safe, as effective and performs as well as or better than the predicate devices.