September 11, 2019

CNSystems Medizintechnik GmbH
Bernd Wellisch
Head of Regulatory
Reininghausstrasse 13
Graz, 8020 At

Re: K183521
Trade/Device Name: CNAP Monitor 500 HD
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DXG
Dated: December 14, 2018
Received: December 19, 2018

Dear Bernd Wellisch:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183521

Device Name
CNAP Monitor 500 HD

Indications for Use *(Describe)*
The CNAP® Monitor 500 HD is intended for the non-invasive continuous monitoring of blood pressure, pulse rate, and the determination of associated derived hemodynamic parameters including cardiac output within hospitals.
The device displays the blood pressure waveform, trends, and numeric for blood pressure, pulse rate, and associated derived hemodynamic parameters. Alarms are generated for blood pressure parameters and pulse rate.
The CNAP® Monitor 500 HD is to be used for adults and is to be operated by healthcare professionals.

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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5 510(k) Summary - CNAP® Monitor 500 HD

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

5.1 Submitter´s information

Submission date	08/06/2019
510(k) submitter	CNSystems Medizintechnik GmbH Reininghausstrasse 13 8020 Graz, Austria Tel: 0043-316-7234560 E-Mail: regulatory@cnsystems.com
Primary contact person	Bernd Wellisch / Head of Regulatory Affairs Tel: 0043-316-723456-702 E-Mail: bernd.wellisch@cnsystems.com
Device name	Non-invasive continuous blood pressure and hemodynamic monitoring system
Trade name	CNAP® Monitor 500 HD
Review panel	Cardiovascular devices
Classification regulation	870.1130, 870.1435
Product code	DXN, DXG
Device class	Class II (two)

5.2 Device information

5.2.1 Primary Predicate Device - CNAP® Monitor 500i, 500at

Clearance number:	K082599
Manufacturer:	CNSystems Medizintechnik AG Reininghausstrasse 13, A-8020 Graz, Austria
This predicate device has not been subject to a design-related recall.	

5.2.2 Secondary Predicate Device - EV1000 Clinical Platform Non-Invasive (NI) and ClearSight Finger Cuffs or ClearSight System, EV1000 Clinical Platform

Clearance number:	K160552
Manufacturer:	Edwards Lifesciences, LLC One Edwards Way, Irvine, California 92614
This predicate device has been subject to a design-related recall class 1, event ID 82456. The CNAP® Monitor 500 HD was assessed regarding the assessed cause and hazard and found to be not affected. See Section 10 and 11 for Details.	

5.2.3 Third Predicate Device – PulsioFlex Monitoring System

Clearance number:	K172259
Manufacturer:	PULSION Medical Systems SE; Maquet Cardiovascular 45 Barbour Pond Drive Wayne, New Jersey 07470
This predicate device has not been subject to a design-related recall.	

5.3 Device Description

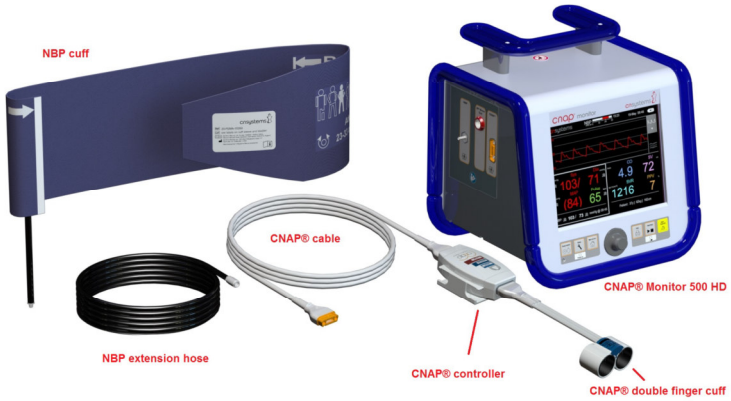

Figure 1 CNAP® Monitor 500 HD with external components

The CNAP® Monitor 500 HD 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 (Advantage 2.0 OEM module by SunTech Inc.) is used for intermittent calibration of the continuous blood pressure curve. Medium priority alarming can be set for blood pressure beat values and pulse rate.

5.4 Indications for use / Intended use

The CNAP® Monitor 500 HD is intended for the non-invasive continuous monitoring of blood pressure, pulse rate, and the determination of associated derived hemodynamic parameters including cardiac output within hospitals. The device displays the blood pressure waveform, trends, and numeric for blood pressure, pulse rate, and associated derived hemodynamic parameters. Alarms are generated for blood pressure parameters and pulse rate.
The CNAP® Monitor 500 HD is to be used for adults and is to be operated by healthcare professionals.

5.5 Comparison of technological characteristics with the predicate device

The hardware of the CNAP® Monitor 500 HD is very similar to the primary predicate CNAP® Monitor 500i, 500at, with following modifications:

Changes to hardware:

- Exchange of the display and adaption of related components (e.g. ferrite)
- Exchange of components and pressure sensors in the CNAP® Controller and related redesign of the printed circuit board (PCB).
- Additional symbol stickers on the housing of the CNAP® Monitor 500 HD

Functional improvements and additional parameters:

- New variability parameter derived from blood pressure curve: PPV.

- New hemodynamic parameters derived from blood pressure curve: CO, SV, SVR, CI, SI, SVRI, and subsequently modified screen layout.
- Improved controllers for the continuous blood pressure measurement function and startup sequence for the continuous blood pressure measurement function.

5.6 Performance data

The Design verification and validation has demonstrated that the CNAP® Monitor 500 HD performs within its specifications and within the limits of the applied performance standards.

The design verification and validation activities for the CNAP® Monitor 500 HD consists of:

- Requirement verification
- Code reviews
- Static code analysis
- Regression testing
- Verification of applicable product standards and Product Requirements
- (Clinical) Performance Validation and (Summative) Usability Validation

5.6.1 Biocompatibility testing

All surface materials have a biocompatibility approval. The materials are not modified during assembling and therefore all certificates remain valid, a new assessment for biocompatibility is not necessary.

The biocompatibility evaluation for CNAP® Monitor 500 HD device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing’” and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process”, as recognized by FDA.

Cytotoxicity, Sensitization, Irritation tests were performed.

5.6.2 Electrical safety and electromagnetic compatibility (EMC), Mechanical and acoustical testing

The Electromagnetic Compatibility and Electrical Safety, according to applicable product standards:

- IEC 60601-1:2005+A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-8:2006+A1:2012
- IEC 80601-2-30:2009

are confirmed by the accredited laboratories OVE AUSTRIAN ELECTOTECHNICAL ASSOCIATION, TÜV Testing Laboratory Vienna, Intertek Testing Services NA and Seibersdorf laboratories.

5.6.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The software for this device was considered as a "major" level of concern, since the CNAP® Monitor 500 HD is a stand-alone non-invasive blood pressure monitoring device with an alarming system.

5.6.4 Animal Testing

Not applicable.

5.6.5 Clinical Testing

For clinical testing and evaluation measurement data from different sources was used to demonstrate that the device is substantially equivalent to the predicate devices.

5.6.6 Performance Data – Conclusion

The clinical performance data demonstrates that the CNAP® Monitor 500 HD performs comparable to the predicate devices for the assessed parameters.

5.7 Conclusion for Substantial Equivalence

CNSystems has concluded that the technological characteristics of the CNAP® Monitor 500 HD are substantial equivalent to the primary predicate device, as it relies on the same hardware platform and measurement principle.

In addition, the technological characteristics regarding the calculation the hemodynamic and variability parameters from the continuous waveform are substantially equivalent in performance to the secondary predicate device.

CNSystems has conducted risk analysis and performed necessary verification and validation activities to demonstrate that the design output of the new device meets the design input requirements.

The CNAP® Monitor 500 HD has been shown to be safe and effective. It is substantial equivalent to the predicate devices for their respective intended uses.