DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 18, 2017

Finapres Medical Systems B.V.
Iris van Uitert
Quality Manager Finapres Medical Systems
Institutenweg 25
7521 PH Enschede
The Netherlands

Re: K160967
Trade/Device Name: Finapres NOVA Noninvasive Hemodynamic Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, DXN, DSB, DQA
Dated: April 12, 2017
Received: April 17, 2017

Dear Iris Van Uitert:

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. 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.

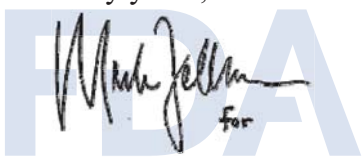
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K160967

Device Name

Finapres NOVA Noninvasive Hemodynamic Monitor

Indications for Use *(Describe)*

The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals, such as heart rate variability (HRV) and Baroreflex sensitivity (BRS).
Cardiac output derived from the flow signal requires a calibration with thermal dilution.

The Finapres NOVA has the option to include additional modules to extend its functionality with ECG and SpO2 measurements and blood pressure calibration.

When the SpO2 module is present, the Finapres NOVA can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate.

When the ECG module is present, the Finapres NOVA can additionally monitor the ECG parameters of a patient and their pulse rate. Alarms concerning the pulse rate will be available from the monitor.

When the blood pressure calibration module is present, the Finapres NOVA can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The Finapres NOVA is intended to be used for subjects above 18 years of age.

The Finapres NOVA is intended for use in hospitals, clinics and research institutions.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

ANS software module addition to the Finapres NOVA – K160967

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

1. Submitter's information

Submitter:	Finapres Medical Systems B.V. Hogehilweg 8 NL-1101 CC Amsterdam The Netherlands Phone number: +31 20 609 0974 Fax Number: +31 20 609 0677 Operator Number: 9051428 Registration number: 3003803088
Contact person:	Iris van Uitert, PhD Quality Manager Phone number: +31 20 609 0974 E-mail:iris.van.uitert@finapres.com

Date of preparation: June 07, 2016

2. Device information Finapres NOVA

Trade name:	Finapres NOVA Noninvasive Hemodynamic Monitor
Common name(s)	Noninvasive Blood Pressure Monitor Hemodynamic Monitor Electrocardiograph Oximeter
Classification name	See Table 1
Device classification	Class II
510(k) number under which it was cleared.	K141460

Table 1. Classification name Finapres NOVA

Classification name	21 CFR Section	Product Code
Noninvasive Blood Pressure Monitor Measurement System	870.1130	DXN
Plethysmograph, Impedance	870.2770	DSB
Oximeter	870.2700	DQA
Cardiac monitor	870.2300	DRT

3. Predicate Device for the proposed change

The Finapres NOVA remains substantially equivalent in design (methodology) and indications for use to the primary predicate shown in Table 2.

The ANS software module is substantially equivalent in design (methodology) to the software algorithms used on the secondary predicate shown in Table 2

The indications for use of the Finapres NOVA is substantially equivalent to the devices shown in Table 2 that has previously been cleared.

Table 2. Predicate devices for the Finapres NOVA with ANS software module

Device name	Manufacturer	510(k)
Primary: Finapres NOVA	Finapres Medical Systems B.V.	K141460
Secondary: TASK FORCE MONITOR 3040	CNSYSTEMS MEDIZINTECHNIK GMBH, Graz, Austria	K014063

4. Description of the ANS software module, Remote Control module and Nova Scope PC application

The Finapres NOVA is an instrument to noninvasively monitor blood pressure and hemodynamic parameters. The Finapres NOVA provides a characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals.

The Finapres NOVA has the option to include four additional modules to extend its functionality with ECG and SpO2 measurements, blood pressure calibration and data transfer to and from the device.

The measurement of blood pressure in a finger is based on the arterial volume-clamp method of the Czech physiologist J. Peñáz, and the Physiocal - physiological calibration - criteria for the proper unloading of the finger arteries of K.H. Wesseling. With this method, finger arterial pressure is measured using a finger cuff and an inflatable bladder in combination with an infrared plethysmograph, which consists of an infrared light source and detector.

The SpO2, upper arm calibration and ECG modules used in the Finapres NOVA are commercially available OEM modules that are used in FDA approved systems. The finger blood pressure measurement module used in the system is similar to other Finapres Medical Systems B.V. devices available on the market. The analog input/output module has been developed by Finapres during the Finapres NOVA development.

The embedded software in the device provides computation of real-time and beat-to-beat blood pressure as well as hemodynamic parameters from the non-invasely measured blood pressure waveform. Hemodynamic parameters include cardiac output based on the modelflow method and total peripheral resistance.

The addition to the Finapres NOVA software covered in this application is mostly related to the addition of a software module called ANS (Autonomous Nervous System). (Para)sympathetic function can be assessed by a physician through arterial Baro Reflex Sensitivity (BRS) testing and Heart Rate Variability (HRV) analysis. The ANS software module calculates additional parameters, derived from pressure and ECG signals measured with the Finapres NOVA, which are related to Baro Reflex Sensitivity and to Heart Rate Variability.

A baroreceptor is a sensory nerve ending in de wall of the aortic arch and carotid bulbus that is sensitive to changes in blood pressure. These baroreceptors act as receptors of

central reflex mechanisms that regulate the blood pressure[1]. The blood pressure is regulated by altering heart rate (baroreflex), cardiac contractility, vasoactivity and humoral activity. The main function of the baroreflex is to maintain a stable blood pressure. To quantify whether the baroreflex is functioning properly the linear regression line of the relation between systolic blood pressure and resulting interbeat interval is estimated. The slope of this linear regression line is defined as the Baro Reflex Sensitivity (BRS) and is to be used in the assessment of the (dys)function of the baroreflex.

Heart rate variability (HRV) is the physiological phenomenon of variation in the time interval between heartbeats. It is determined using the beat-to-beat interval.

Using this additional software module, the Finapres NOVA only presents parameters derived from the interbeat interval (HRV) and blood pressure (BRS) to the user. It is up to the user to draw conclusions on whether these values are normal or abnormal.

The additional Remote Control Module provides the possibility to monitor and control a Finapres Nova from a PC. This can be achieved by establishing a network connection from a PC to the Finapres Nova. Two types of connections can be made: one that is restricted to viewing and one that allows full control of the Finapres Nova.

The additional Nova Scope PC application is used to view and review measurement files recorded with the Finapres Nova on a PC instead of on the NOVA instrument itself.

5. Indications for use

The Finapres NOVA is intended to be used with patients who have a need for a noninvasive blood pressure and hemodynamic monitor. The noninvasive blood pressure waveform is measured on the subject's finger. The Finapres NOVA provides a noninvasive characterization of the arterial circulation and its beat-to-beat variability in pressure and flow and in various hemodynamic parameters derived from these pressure and flow signals, such as heart rate variability (HRV) and Baroreflex sensitivity (BRS).
Cardiac output derived from the flow signal requires a calibration with thermal dilution.

The Finapres NOVA has the option to include additional modules to extend its functionality with ECG and SpO2 measurements and blood pressure calibration.

When the SpO2 module is present, the Finapres NOVA can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate.

When the ECG module is present, the Finapres NOVA can additionally monitor the ECG parameters of a patient and their pulse rate. Alarms concerning the pulse rate will be available from the monitor.

When the blood pressure calibration module is present, the Finapres NOVA can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration.

The Finapres NOVA is intended to be used for subjects above 18 years of age.

The Finapres NOVA is intended for use in hospitals, clinics and research institutions.

[1] http://medical-dictionary.thefreedictionary.com/baroreceptor and http://encyclopedia.thefreedictionary.com/baroreflex

6. Intended Use of the additional software modules

Using the ANS software module, a physician can determine per patient whether that specific patient has normal or abnormal BRS and HRV values in conjunction with other hemodynamic parameters. The threshold between normal and abnormal values can differ per patient and is at the discretion of the physician.

The Remote Control module and Nova Scope PC application have the same intended use as the original K141460 submission, they are merely used for remote control of the Nova and for viewing recorded files on a PC.

7. Summary of Technical Comparison with predicate device

The modified Finapres NOVA has the following similarities with the TASK FORCE MONITOR 3040:

- Both devices have the same indication for use.
- Both devices use the same operating principles.
- The ANS software application of the Finapres NOVA and the algorithms used in the Task Force Monitor are equivalent in calculated HRV an BRS parameters

In summary, the ANS Basic software module used on the Finapres NOVA described in this submission is, in our opinion, substantially equivalent to the predicate device.

8. Non-clinical performance data for substantial equivalence determination

Software performance of the overall Finapres NOVA software, including this module, was established according to FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, consistent with moderate level of concern.

The performance of the HRV and BRS algorithm was tested and found to be substantially equivalent with the performance of the algorithms of our secondary predicate device, the TASK FORCE MONITOR 3040

The verification tests performed demonstrate that the new software module on the Finapres NOVA met all applicable requirements.

9. Clinical performance data for substantial equivalence determination

Clinical performance data was not required to demonstrate substantial equivalence.

10. Conclusion

On basis of the information above, it is concluded that the device is as safe, as effective, and performs as well as or better than the predicate device.