November 6, 2018

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

Re: K173916
Trade/Device Name: Finapres NOVA Noninvasive Hemodynamic Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DSB, DQA, DRT
Dated: September 24, 2018
Received: September 26, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.11.06 11:21:49 -05'00'

for: 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Finapres NOVA

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 centers.

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.

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510(k) Summary

Change of front-end unit of Finapres Nova to front-end unit Nano Core (FEU NC)

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. Institutenweg 25 7521 PH Enschede The Netherlands Phone number: +31 88 115 2700 Fax Number: +31 20 609 0677 Operator Number: 9051428 Registration number: 3003803088
Contact person:	Iris van Uitert, PhD Quality Manager Phone number: +31 88 115 2700 E-mail:iris.van.uitert@finapres.com

Date of preparation: November 1, 2018

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 previously cleared.	K141460 and K160967

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 additional AT software module (not present in K141460) 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. Primary and secondary predicate devices for the Finapres Nova with front-end unit Nano Core

Device name	Manufacturer	510(k)
Primary: Finapres Nova	Finapres Medical Systems	K141460
Secondary: Finapres Nova	Finapres Medical Systems	K160967

4. Description of the Finapres with FEU NC

The Finapres NOVA with FEU NC is based on existing Finapres Medical Systems B.V. product: the Finapres Nova. The changes between the Finapres NOVA with FEU NC and the previous systems are described below.

The current hardware that generates pressure in the Finapres NOVA contains components which are end-of-life. Therefore, they will need to be replaced. It was decided not to redesign these PCBs, but to redesign the whole pressure control hardware for reasons mentioned below.

In the new NOVA with FEU NC, the wrist unit FEU of the current NOVA system is replaced by the wrist unit FEU Nano Core. The FEU Nano Core wrist unit has the capability of generating pressure in the wrist unit, whereas with the FEU wrist unit the pressure was generated in the NOVA base station. This means that the pump, printed circuit boards (PCBs) and FEU have been replaced by a new power supply PCB and the FEU NC. By moving the pressure generation and control to the Nano Core wrist unit, there is no need for a pressure cable from the base station to the wrist unit anymore, which increases the mobility of the system and patient.

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.

Using the blood pressure calibration module, 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 centers.

6. Comparison of technical characteristics to predicate devices K141460 and K160967

The modified Finapres NOVA with FEU NC has the following similarities with the Finapres Nova from submission K141460 and K160967:

- Both devices use the same operating principles and use the same algorithms, see Table 3 below.

In summary, the Finapres NOVA with FEU NC described in this submission is, in our opinion, substantially equivalent to the predicate device Finapres NOVA.

Table 3: Comparison of the technological characteristics of the two predicate Finapres NOVAs (K141460 and K160967) and the Finapres NOVA with FEU NC

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
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. 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.	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.	The Finapres NOVA with FEU NC 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 with FEU NC 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 with FEU NC has the option to include five additional modules to extend its functionality with ECG, SpO2, blood pressure calibration and data transfer to and from the device.	Yes, see note 1 below this table.

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
	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 a professional medical environment.	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 centers.	When the SpO2 module is present, the Finapres NOVA with FEU NC can additionally monitor the functional oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate. When the ECG module is present, the Finapres NOVA with FEU NC 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 with FEU NC can additionally provide an upper arm non-invasive blood pressure measurement to determine the blood pressure value for calibration. The Finapres NOVA with FEU NC is intended to be used for subjects above 18 years of age. The Finapres NOVA is intended for use in hospitals, clinics and research centers, see note 1 below this table.	
Measurement method / Algorithm	The Finapres NOVA uses the algorithm arterial volume-clamp method of J. Peñáz and the Physiocal criteria (Servo SelfAdjust) of K.H. Wesseling for the continuous measurement of blood pressure	The Finapres NOVA uses the algorithm arterial volume-clamp method of J. Peñáz and the Physiocal criteria (Servo SelfAdjust) of K.H. Wesseling for the continuous measurement of blood pressure	The Finapres NOVA with FEU NC uses the algorithm arterial volume-clamp method of J. Peñáz and the Physiocal criteria (Servo SelfAdjust) of K.H. Wesseling for the continuous measurement of blood pressure	No

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
	The Finapres NOVA uses the NOVAScope/Modelflow software technology to analyze the trend hemodynamic parameters on the device and main module firmware to control the measurement	The Finapres NOVA uses the NOVAScope/Modelflow software technology to analyze the trend hemodynamic parameters on the device and main module firmware to control the measurement	The Finapres NOVA with FEU NC uses the NOVAScope/Modelflow software technology to analyze the trend hemodynamic parameters on the device. The firmware of the FEU NC controls the measurement	Yes, see note 2 below this table
Maximum measurement duration	Maximum 24 h continuous measurement	Maximum 24 h continuous measurement	Maximum 24 h continuous measurement	No
How supplied	Stationary Base station to which subject is connected and to generate pressure	Stationary Base station to which subject is connected and to generate pressure	Stationary Base station to which subject is connected (no pressure generation)	Yes, different materials and design, see note 3 below this table
	Front-end unit to interface the signals from the electronics and air supply in the main module to the finger cuffs	Front-end unit to interface the signals from the electronics and air supply in the main module to the finger cuffs	Front-end unit to generate air pressure signals to and interpret electronic signals from the finger cuffs. Receives data and power from base station, sends blood pressure data to base station	Yes, different material of the FEU cable and design, see note 3 below this table
	Finger cuffs for continuous blood pressure measurement	Finger cuffs for continuous blood pressure measurement	Finger cuffs for continuous blood pressure measurement	no
	Hydrostatic height correction unit compensates for vertical movement of the hand relative to heart level (optional).	Hydrostatic height correction unit compensates for vertical movement of the hand relative to heart level (optional).	Hydrostatic height correction unit compensates for vertical movement of the hand relative to heart level (optional).	no
	Analog input/output module (optional)	Analog input/output module (optional)	Analog input/output module (optional)	no
	Upper arm calibration module with arm cuff for pressure calibration (optional)	Upper arm calibration module with arm cuff for pressure calibration (optional)	Upper arm calibration module with arm cuff for pressure calibration	no
	ECG module with 3 or 5 lead ECG cable (optional)	ECG module with 3 or 5 lead ECG cable (optional)	ECG module with 3 or 5 lead ECG cable (optional)	no
	SpO2 module with SpO2 finger clip (optional)	SpO2 module with SpO2 finger clip (optional)	SpO2 module with SpO2 finger clip (optional)	no

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
	No separate software package for data downloading. Finapres wave form data can be analyzed by the NOVAScope software on the Finapres NOVA.	No separate software package for data downloading. Finapres wave form data can be analyzed by the NOVAScope software on the Finapres NOVA.	No separate software package for data downloading. Finapres wave form data can be analyzed by the NOVAScope software on the Finapres NOVA.	no
Required accessories				
Finger cuffs	Adult sizes: large, medium, small	Adult sizes: large, medium, small	Adult sizes: large, medium, small	Yes, different connector to FEU NC, which has no effect on functionality or accuracy of the measurement
Height Correction unit	Height correction unit for connection to front-end unit	Height correction unit for connection to front-end unit	Height correction unit for connection to front-end unit Nano Core	Yes, different connector to FEU NC, which has no effect on functionality or accuracy of the measurement
Display type	LED-backlit LCD	LED-backlit LCD	LED-backlit LCD	No
Controls	Touch screen	Touch screen	Touch screen	no
Battery	No	No	No	no
Measuring Capability				
Systolic BP	Yes, continuously	Yes, continuously	Yes, continuously	no
Diastolic BP	Yes, continuously	Yes, continuously	Yes, continuously	no
Mean BP	Yes, continuously	Yes, continuously	Yes, continuously	no
Pulse rate	Yes, continuously	Yes, continuously	Yes, continuously	no
Accuracy				
Blood pressure Finger cuff	1% of full scale (max. ± 3 mmHg)	1% of full scale (max. ± 3 mmHg)	1% of full scale (max. ± 3 mmHg)	no

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
Hydrostatic height	2% of full scale (max. ± 3 mmHg)	2% of full scale (max. ± 3 mmHg)	2% of full scale (max. ± 3 mmHg)	no
Pulse rate (from finger cuff)	(rate [bpm]/60)% (± 5 bpm average)	(rate [bpm]/60)% (± 5 bpm average)	(rate [bpm]/60)% (± 5 bpm average)	no
Interbeat interval	Max 10 ms (non-accumulating)	Max 10 ms (non-accumulating)	Max 10 ms (non-accumulating)	no
Clinical Accuracy:				
BP(intra-arterial)	Does conform to IEC 81060-2:2009 and AAMI SP10 :2002 after calibration	Does conform to IEC 81060-2:2009 and AAMI SP10 :2002 after calibration	Does conform to AAMI ANSI ISO 81060-2:2013 and AAMI SP10 :2002	Yes. The Finapres NOVA was clinically tested to proof compliance with ISO 81060-2:2013
Digital display				
Systolic BP	Yes	Yes	Yes	no
Diastolic BP	Yes	Yes	Yes	no
Mean BP	Yes	Yes	Yes	no
Pulse rate	Yes	Yes	Yes	no
Waveform				
BP	Yes	Yes	Yes	no
Hydrostatic height signal	Yes	Yes	Yes	no
Trending				
Systolic BP	Yes	Yes	Yes	no
Diastolic BP	Yes	Yes	Yes	no
Mean BP	Yes	Yes	Yes	no
Pulse rate	Yes	Yes	Yes	no

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
Ranges:				
BP	0-350 mmHg	0-350 mmHg	0-330 mmHg	Yes, however difference is not clinically significant. Similar devices in the field usually show range of 0-300 mmHg
Pulse rate finger cuff	0-240 bpm	0-240 bpm	0-214 bpm	Yes, however difference is not clinically significant. See note 4 below this table
Hydrostatic height signal	-100 to +100 mmHg	-100 to +100 mmHg	-100 to +100 mmHg	no
Patient population	Adults	Adults	Adults	no
Alarms	The Finapres NOVA is fully automatic, to reduce user error. A measurement is automatically suspended after an operational error, such as disconnecting the air tube to the finger cuff Optionally, when ECG module is present: visual alarms for heart rate only	The Finapres NOVA is fully automatic, to reduce user error. A measurement is automatically suspended after an operational error, such as disconnecting the air tube to the finger cuff Optionally, when ECG module is present: visual alarms for heart rate only	The Finapres NOVA with FEU NC is fully automatic, to reduce user error. A measurement is automatically suspended after an operational error, such as disconnecting the air tube to the finger cuff Optionally, when ECG module is present: visual alarms for heart rate only	no
No pulse in case of low quality signal/System failure alert	Yes	Yes	Yes	no
Environmental				
Operating temperature	10-35°C (50 – 95 °F)	10-35°C (50 – 95 °F)	10-35°C (50 – 95 °F)	no

Parameter	Finapres NOVA K141460	Finapres NOVA K160967	Finapres NOVA with FEU NC	Different?
Humidity	5-90%, non-condensing	5-90%, non-condensing	5-90%, non-condensing	no
Altitude range	700-1100 hPa	700-1100 hPa	700-1100 hPa	no
Size				
Base station	13 x 11 x 10 in (33 x 28 x 26 cm)	13 x 11 x 10 in (33 x 28 x 26 cm)	13 x 11 x 10 in (33 x 28 x 26 cm)	no
Patient-interface module	2.8 x 2.0 x 1.2 in (6.5 x 5 x 3 cm) Frontend unit	2.8 x 2.0 x 1.2 in (6.5 x 5 x 3 cm) Frontend unit	3.7 x 2.3 x 1.4 in (9.5 x 6.0 x 3.5 cm) Frontend unit	Yes, FEU NC is larger, as the new FEU has to host pressure generation. However, weight of the FEU is lower, see weight below, and therefore the larger size is deemed acceptable
Weight	11 lbs. (5 kg) base station	11 lbs. (5 kg) base station	9 lbs. (4 kg) base station	Yes, pump is removed from base station. This does not affect the performance of the base station.
	2 lbs (0.9 kg) Frontend unit (including cables)	2 lbs (0.9 kg) Frontend unit (including cables)	0.7 lbs (0.3 kg) Frontend unit (including cables)	Yes, cable is lighter, as the cable does not contain a pressure conduit. Cable is therefore also thinner. FEU NC is thus more comfortable to wear.
AC power	100-240 Vac, 50/60 Hz	100-240 Vac, 50/60 Hz	100-240 Vac, 50/60 Hz	no

Note 1: The Finapres NOVA is intended for use in a medical professional environment whereas the Finapres NOVA with FEU NC is intended for use in hospitals, clinics and research centers. The intended environment for the Finapres NOVA with FEU NC was specified more precisely to give a more explicit indication to the users of where the system can be used.

Note 2: The NOVAScope/Modelflow software of the NOVA is used as user interface, to start and stop the measurement and for recording of signals; firmware of the FEU NC is used to measure blood pressure signals, control the pressure and process plethysmograph data (formerly performed by the main module firmware in the NOVA base station). Algorithms from main module firmware were copied and translated into a new programming language. No new functionality was added in software.

Note 3: Hardware of FEU NC: Casing consists of aluminum and plastic, interior has 3D printed manifolds, valves, voice coil actuated bellows, pump and PCB with micro controller, were the current FEU consists of a PCB with proportional valve in an aluminum casing. The FEU NC receives power from NOVA base station. Pump and main module PCBs were removed from NOVA base station, FEU NC supply PCB was added and cables were rerouted. Connector to NOVA base station has changed for FEU NC. Materials that come into patient contact were unchanged for the wristband but changed to TPU for the cable.

Note 4: Maximum heart rates for adults can be calculated using the Tanaka method (208 - (0.7 x Age), see "Age-predicted maximal heart rate revisited, Tanaka et al., 2001, J. Am. Coll. Cardiol."), which shows that the maximum heart rate for a 18 year old male adult is around 195 ± 10 beats per minute maximally. Thus, 214 BPM is considered a sufficient heart rate limit for measurements in adults.

6.1. AT software module in predicate device K160967: difference between K141460 and K160967.

The AT software module of the modified Finapres NOVA with FEU NC contains algorithms to calculate BRS and HRV parameters. These algorithms are the same as used in the secondary predicate device indicated in Table 4. This AT Software module is furthermore the only difference between the two predicate devices K141460 and K160967.

Table 4. Secondary predicate devices for the Finapres NOVA with FEU NC

Device name	Manufacturer	510(k)
Finapres NOVA	Finapres Medical Systems B.V.	K160967

6.2. Accessories: difference between K141460 and K160967

The following table shows accessories that can be used in combination with the Finapres NOVA and clearance numbers for these accessories:

Table 5. Accessories K160967

Accessory name	Cleared in submission
Frontend Unit NC (Nano Core)	Current submission
Height correction unit NC	Current submission
Finger cuffs: • S(mall) finger cuff NC (white) • M(edium) finger cuff NC (beige) • L(arge) finger cuff NC (blue)	Current submission
Power cables	K141460
ECG cables: • 3 leads US • 5 leads US	K141460
SpO2 cables: • Interface cable • Finger clip	K141460
Arm cuff cables: • Extension Tube • Arm cuff (4 sizes available)	K141460

7. Non-clinical performance data for substantial equivalence determination

Testing of the Finapres NOVA was performed according to medical device safety standards shown in Table 6 .

Table 6: standards that the device was tested against

Standard number	Standard name
AAMI / ANSI ES 60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2007	Medical electrical equipment – Part 1-2: General requirements for safety –Electromagnetic compatibility – Requirements and tests
IEC 60601-1-8: 2006 & A1:2012	Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-27 Edition 3.0 2011-03	Medical electrical equipment – Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment

IEC 80601-2-30:2009 & A1:2013	Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 14971:2007	Medical devices – Risk management – Application of risk management to medical devices
IEC 62304:2006	Medical device software – software life cycle processes
IEC 62366:2007/(R)2013	Medical devices – Application of usability engineering to medical devices.
ISO 10993-1:2009/(R) 2013	Biological evaluation of medical devices – Part 1: Evaluation and testing
ISO 10993-5:2009	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software performance of the overall Finapres NOVA software, including that of the FEU NC, 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 verification tests performed demonstrate that the new FEU NC met all applicable requirements and that it is substantially equivalent to its predecessor Finapres NOVA.

7.1. Bench testing

Finapres has performed a technical bench validation test in which the pressure generation and registration of the predicate system NOVA and the NOVA with FEU NC are compared. The range, resolution, and accuracy of the pressure sensors of the NOVA with FEU NC is equivalent to the predicate system NOVA, as is the range, accuracy, and dynamic response of the pressure controller.

Additionally, during the bench tests, the range and noise of the registration of the photodiode current of the plethysmograph of the predicate device and NOVA with FEU NC was compared. The performance of the photodiode current registration demonstrated equivalence in comparison to the predicate device.

7.2. Comparison of electronic and software components of predicate device that were changed into FEU NC firmware

Extensive analysis was performed on electronic circuits and software algorithms that performed photodiode current processing, closed loop functions and blood pressure measurement tasks in the predicate NOVA system. The functionality of the Finapres NOVA main module firmware was implemented in FEU NC firmware: first, pseudo code was written of the software and electronics of the predicate device to preserve functionality and create an independent understanding of the algorithms. In this way, implementation-specific logic for the electronic schemes and software language of the NOVA predicate device was removed. Second, development of the software in C++ itself was performed according to ISO 62304. In this way, the functionality is maintained.

7.3. Measuring usability performance

Usability studies have been performed in an early stage (at the start of the design phase) using non-functional mock-ups and after a prototype was finished. Studies were performed according to the usability standard ISO 62366. It was concluded from these usability studies that the FEU NC performed in accordance with its intended use, with use-related risks being adequately mitigated.

7.4. Hemodynamic parameter validation

With respect to K141460, none of the physiological tracking algorithms (the volume clamp method termed Physiocal) or sensors (finger cuff) have changed The only part that was changed is the part that generates the pressure for the finger cuff. To demonstrate that the hemodynamic parameters are still calculated in the same way as with the predicate K141460, only proof is required for the fact that the bandwidth of the part that generates the cuff pressure is such that the dynamic arterial pressure waveform will be followed accurately. Benchtop tests were performed using a finger simulator developed for that purpose, which can provoke dynamic changes in the generated cuff pressure waveform, mimicking the blood pressure waveform. During the bench top testing it was shown for a wide range of heart rate, stroke volume and cardiac output, tested with 7 different simulator models in 99 measurements, that the output of K141460 and K173916 is comparable. Results were sufficient to demonstrate substantial equivalence.

8. Clinical performance data for substantial equivalence determination

A clinical investigation was performed according to the requirement of ISO 81060-2:2013 which proves the Finapres NOVA with FEU NC meets the accuracy requirement regarding blood pressure measurements of this standard.

This clinical data was also used to calculate the hemodynamic parameters based on both the invasive reference and K173916.

9. 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 devices.