



December 21, 2018

North-vision Tech. Inc.  
% Shin-Ban Tsai  
USA Presentative to North-vision Tech. Inc.  
Pan-America Hyperbarics, Inc.  
3528 Robin Road  
Plano, Texas 75075

Re: K173036

Trade/Device Name: North-vision Elegant-1000 Series of Multi-parameter Patient Monitor  
Regulation Number: 21 CFR 870.2300  
Regulation Name: Cardiac Monitor (Including Cardiometer and Rate Alarm)  
Regulatory Class: Class II  
Product Code: MWI, DXN, DQA  
Dated: December 6, 2018  
Received: December 6, 2018

Dear Shin-Ban Tsai:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Arielle Drummond -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K173036

Device Name

North-vision Elegant-1000 Series of Multi-parameter Patient Monitor

Indications for Use (Describe)

The North-vision Elegant-1000 Series of Multi-parameter Patient Monitor are intended to monitor, display and record physiological signs of adult, pediatric patients. With the functions of near real-time recording and displaying parameters ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, it allows comprehensive analysis of patient's physiological conditions. This apparatus is applicable for use in hospitals, clinics, and practitioner's office. The operation should be carried out by qualified professionals only.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## 510(K) SUMMARY

### 1. Name and Address of Submitters

North-vision Tech Inc.

1<sup>st</sup> Fl., No.15, Gongye E. 2<sup>nd</sup> Rd., East Dist., Hsinchu City 30075, Taiwan R.O.C.

Tel: 886-3-577-1038

Fax:886-3-577-1039

#### Contact Person:

Mr. Albert Huang, CEO Tel:

886-3-577-1038 ext.601

E-mail: ahuang@north-vision.com

### 2. Device Name:

North-vision Elegant-1000 Series of Multi-parameter Patient Monitor

#### Common or usual Names:

Beside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor and Anesthesia monitor.

#### Classification:

The device has been classified as Class II

by the “Cardiovascular” Device Classification Panel

under 21 CFR Part 870.2300, “Monitor, physiological, patient (without arrhythmia detection or alarms).” as **MWI**

under 21 CFT 870.1130, “Noninvasive blood pressure measurement system” as **DXN**

by the “Anesthesiology” Device Classification Panel

under 21 CFT 870.2700, “Oximeter” as **DQA**

**Product Code: MWI**

**Second Product Code: DXN, DQA**

### 3. Legally Marketed Predicate:

CREATIVE Patient Monitor, UP-7000 per 510(k)K123711, commercial distribution certification dated Oct. 1, 2013.

### 4. Device Description:

The Elegant-1000 Series are intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. They are modular designed patient Monitors. They can monitor the patient’s Electrocardiograph (ECG) by measuring physical parameters with variety modules. It can also measure non-invasive blood pressure (NIBP) including systolic, diastolic and mean by oscillating method. It can detect the blood oxygen saturation (SpO<sub>2</sub>) and pulse rate (PR) by the photoelectric method.

The accessories and the sensors will transfer the physical parameters into electrical signal, which will be collected and amplified by the circuit in the device. After CPU analyzing and calculating the parameters are displayed on the screen in a graphical representation and it can record and/or print if necessary. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits.

**5. Indications for Use:**

The North-vision Elegant-1000 Series of Multi-parameter Patient Monitor are intended to monitor, display and record physiological signs of adult, pediatric patients. With the functions of near real-time recording and displaying parameters ECG, heart rate, non-invasive blood pressure, functional oxygen saturation, it allows comprehensive analysis of patient’s physiological conditions. This apparatus is applicable for use in hospitals, clinics, and practitioner’s office. The operation should be carried out by qualified professionals only.

**6. Equivalent Device Comparison Table:**

**SUBSTANTIAL EQUIVALENCE CHART**

<b>Brand and Product</b>	<b>North-vision Multi-parameter Patient Monitor Elegant-1000 Series (Elegant-1100/1080/1070)</b>	<b>SHENZHEN CREATIVE Patient Monitor (UP-7000)</b>	<b>Significant Differences</b>	
<b>510(k) Number</b>	K173036	K123711	N/A	
<b>Product Code</b>	MWI	MWI	Equivalent	
<b>Regulation Number</b>	870.2300	870.2300	Equivalent	
<b>Secondary Product Code</b>	DXN, DQA	DXN, DQA, CCK	Equivalent <b>The predicate device have one more Secondary Product Code CCK</b>	
<b>Intended use/ Indications for use</b>	<p>The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility.</p> <p>The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms.</p> <p>The device is also intended to monitor ECG, heart rate, pulse rate, blood oxygen saturation (SpO<sub>2</sub>), non-invasive blood pressure(NIBP)</p>	<p>The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility.</p> <p>The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms.</p> <p>The device is also intended to monitor ECG, heart rate, pulse rate, blood oxygen saturation (SpO<sub>2</sub>), non-invasive blood pressure(NIBP)</p>	Equivalent	
<b>Intended Population</b>	Adult, Pediatric	Adult, Pediatric	Equivalent	
<b>General Technical Characteristics</b>				
<b>Energy</b>	AC Power	100 to 240VAC, 50/60Hz	100 to 240VAC, 50/60Hz	Equivalent

<b>Source</b>	DC Battery	Li-Ion	Li-Ion	Equivalent
<b>Mechanism of Action</b>	Data Acquisition	Data Acquisition	Data Acquisition	Equivalent
<b>Pulse Oximetry</b>	Waveform and Numeric	Waveform and Numeric	Waveform and Numeric	Equivalent
<b>NIBP</b>	Oscillometric	Oscillometric	Oscillometric	Equivalent
<b>Mode of operation</b>	Continuous	Continuous	Continuous	Equivalent
<b>Software</b>	Yes	Yes	Yes	Equivalent
<b>Electrical Safety Testing Passed</b>	Yes	Yes	Yes	Equivalent
<b>Electromagnetic Testing Passed</b>	Yes	Yes	Yes	Equivalent
<b>ECG Trunk Cables and Leadwires Testing Passed</b>	Yes	Yes	Yes	Equivalent
<b>Outline and Outlook</b>				
<b>Measuring parameters</b>	Elegant-1100: ECG, NIBP, SpO <sub>2</sub> , Alarm, PR, HR Elegant-1080: NIBP, SpO <sub>2</sub> , Alarm, PR Elegant-1070: ECG, NIBP, SpO <sub>2</sub> , Alarm, PR, HR	ECG, NIBP, SpO <sub>2</sub> , Alarm, PR, HR, ETCO <sub>2</sub>		Equivalent
<b>LCD Panel</b>	Color TFT type LCD Elegant-1100: 10-inch high resolution Elegant-1080: 7-inch high resolution Elegant-1070: 3.5-inch high resolution	Color TFT type LCD 12.1-inch high resolution		Same TFT LCD, but Panel size different
<b>Dimensions</b>	Elegant-1100: 275mm x 140mm x 240mm Elegant-1080: 180mm x 190mm x 280mm Elegant-1070: 195mm x 85mm x 150mm	500(L) × 320(W) × 460(H) mm		Dimensions different

<b>Accessories especially for Sensors</b>			
SpO2 Probe Sensor (Configuration/ Geometry)	Internal Sensor (build-in)	Internal Sensor (build-in)	Equivalent
	Sensing Algorithm: by using Penetrate Type of LED Light cross test body like finger.	Sensing Algorithm: by using Penetrate Type of LED Light cross test body like finger.	
	Light Sources: by using wave length LEDs, located in Red and Infrared.	Light Sources: by using wave length LEDs, located in Red and Infrared.	
	Calculation of SpO <sub>2</sub> value: by data source with calculation formula of $[HbO_2/(HbO_2 + Hb)]$	Calculation of SpO <sub>2</sub> value: by data source with calculation formula of $[HbO_2/(HbO_2 + Hb)]$	
NIBP Sensor	Cuff by pressure sensor	Cuff by pressure sensor	Equivalent
ECG Cable	Leadwires with disposable electrode	Leadwires with disposable electrode	Equivalent
<b>Chemical Composition to Human body of Sensors</b>			
NIBP Cuff	Nylon (Polycaproamide)	Nylon (Polycaproamide)	Equivalent
SPO <sub>2</sub> Probe	Silicone Rubber	Silicone Rubber	Equivalent
Disposable electrode	Conductive hydrogel (White polyethylene /EVA copolymer foam)	Conductive hydrogel (White polyethylene /EVA copolymer foam)	Equivalent
<b>ECG Technical Characteristics (Only for Elegant-1100 and Elegant-1070)</b>			
ECG noise level	$\leq 30\mu V_{p,p}$	$\leq 30\mu V_{p,p}$	Equivalent
Input impedance	$\geq 5M\Omega$	$\geq 5M\Omega$	Equivalent
Common-mode rejection ratio (CMRR)	$\geq 80dB$	$\geq 80dB$	Equivalent
ECG Heart Rate Measuring Range	10~300bpm( $\pm 2bpm$ )	15~350bpm( $\pm 2bpm$ )	Equivalent
ECG Channel	7-channel waveforms display	7-channel waveforms display	Equivalent
Sensitivity selection	$\times 1/4, \times 1/2, \times 1, \times 2, \times 4, Auto$	$\times 1/2, \times 1, \times 2, \times 4, Auto$	Equivalent, but our device has one more selection than predicate device
ECG Leads	3 or 5 lead ECG	3 or 5 lead ECG	Equivalent

<b>NIBP Technical Characteristics (For All devices)</b>			
NIBP Measuring Method	Oscillometric	Oscillometric	Equivalent
NIBP Monitoring Range	Systolic: 20mmHg~290mmHg Diastolic: 10mmHg~260mmHg Mean: 15mmHg~275mmHg	Systolic: 40mmHg~255mmHg Diastolic: 10mmHg~195mmHg Mean: 21mmHg~215mmHg	Equivalent, but our measuring range is wider than predicate device
NIBP Measuring Accuracy	Systolic : ±5 mmHg Diastolic : ±5 mmHg MAP: ±5 mmHg	Systolic : ±5 mmHg Diastolic : ±5 mmHg MAP: ±5 mmHg	Equivalent
<b>SpO<sub>2</sub> Technical Characteristics (For All devices)</b>			
SpO <sub>2</sub> Measuring Range	0% ~ 100% Oxygen saturation	35% ~ 100% Oxygen saturation	Equivalent, but our measuring range is wider than predicate device
SpO <sub>2</sub> Measuring Accuracy	70 ~ 100% : ±2%	70 ~ 100% : ±3%	Equivalent, but our measuring accuracy is better than predicate device
SpO <sub>2</sub> Pulse Rate Measuring Range	15bpm~300bpm	30bpm~240bpm	Equivalent, but our measuring range is wider than predicate device
SpO <sub>2</sub> Pulse Rate Accuracy	±2bpm	±2bpm	Equivalent
<b>Battery</b>			
Battery Charging time (during non-monitoring)	Elegant-1100, Elegant-1080: 4hrs Elegant-1070: 3hrs	4hrs	Equivalent
Battery operation time	Elegant-1100, Elegant-1080: 5hrs Elegant-1070: 3hrs	5hrs	Equivalent

## 7. Performance Specifications

Brand and Product Items	North-vision Elegant-1100	North-vision Elegant-1080	North-vision Elegant-1070
Specification	NIBP, SpO <sub>2</sub> , ECG, Alarm, PR, HR	NIBP, SpO <sub>2</sub> , Alarm, PR	NIBP, SpO <sub>2</sub> , ECG, Alarm, PR, HR
Intended to use	The device is intended to monitor ECG, heart rate, pulse rate, blood oxygen saturation(SpO <sub>2</sub> ), non-invasive blood pressure(NIBP).	The device is intended to monitor, pulse rate, blood oxygen saturation(SpO <sub>2</sub> ), non-invasive blood pressure(NIBP).	The device is intended to monitor ECG, heart rate, pulse rate, blood oxygen saturation(SpO <sub>2</sub> ), non-invasive blood pressure(NIBP)
Size	275mm x 240mm x 140mm	180mm x 280mm x 190mm	195mm x 150mm x 85mm
LCD Panel	10.4 inches TFT color LCD	3.5 inches TFT color LCD	7 inches TFT color LCD
NIBP Measuring Method	Oscillometric	Oscillometric	Oscillometric
NIBP Monitoring Range	Systolic: 20mmHg~290mmHg Diastolic: 10mmHg~260mmHg Mean: 15mmHg~275mmHg	Systolic: 20mmHg~290mmHg Diastolic: 10mmHg~260mmHg Mean: 15mmHg~275mmHg	Systolic: 20mmHg~290mmHg Diastolic: 10mmHg~260mmHg Mean: 15mmHg~275mmHg
NIBP Measuring Accuracy	Systolic : ±5 mmHg Diastolic : ±5 mmHg MAP: ±5 mmHg	Systolic : ±5 mmHg Diastolic : ±5 mmHg MAP: ±5 mmHg	Systolic : ±5 mmHg Diastolic : ±5 mmHg MAP: ±5 mmHg
SpO <sub>2</sub> Measuring Range	0% ~ 100% Oxygen saturation	0% ~ 100% Oxygen saturation	0% ~ 100% Oxygen saturation
SpO <sub>2</sub> Measuring Accuracy	70 ~ 100% : ±2%	70 ~ 100% : ±2%	70 ~ 100% : ±2%
SpO <sub>2</sub> Pulse Rate Measuring Range	15bpm~300bpm	15bpm~300bpm	15bpm~300bpm
ECG Leads	3 or 5	N/A	3 or 5
ECG Heart Rate Measuring Range	15~300bpm(±2bpm)	N/A	15~300bpm(±2bpm)

Note:

1. Elegant-1100 and Elegant-1070 are designed for full function which include ECG, NIBP, SpO<sub>2</sub>.
2. Elegant-1070 is especially designed for its compact size which can be carried on for the portable purpose.

## 8. Non-clinical tests performed that support a determination of substantial equivalence

As part of demonstrating safety and effectiveness of Elegant-1000 Series and in showing substantial equivalence to the predicate devices that are subject to 510(k) submission, North-vision Tech. Inc. completed a number of Non-clinical performance tests against applicable standards. All the Non-clinical tests performed support a determination of substantial equivalence. Following is List of Summary for these Tests.

### Performance Standards Testing Summary:

Test		Pass/fail Criteria	Results
1	Electrical safety	Compliance to <b>IEC 60601-1:2012</b> Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Passed
2	Electromagnetic Compatibility	Compliance to <b>IEC 60601-1-2:2007</b> Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Passed
3	Multifunction Patient Monitor	Compliance to <b>EN 60601-2-49:2001</b> Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment	Passed
4	Alarms	Compliance to <b>IEC 60601-1-8:2012</b> 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	Passed
5	Biocompatibility	Compliance to <b>ISO 10993-1:2009</b> Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Passed
6	Risk Management	Compliance to <b>ISO 14971:2012</b> - Application of risk Management to medical devices	Passed
7	Software	Compliance to <b>IEC 62304:2015</b> Medical device software - Software life-cycle processes	Passed
8	ECG	Compliance to <b>IEC 60601-2-27:2011</b> Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	Passed
9	Pulse Oximeter	Compliance to <b>ISO 80601-2-61:2011</b> Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment	Passed
10	NIBP	Compliance to <b>IEC 80601-2-30:2013</b> <b>ANSI/AAMI/ISO 81060-2:2013</b> - Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	Passed
11	Usability	Compliance to <b>IEC 62366:2014</b> Medical devices - Consolidated Version Application of usability engineering to medical devices	Passed
12	Batteries	Compliance to <b>IEC 62133</b> Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	Passed
12	ECG Trunk Cables and Leadwires	Compliance to <b>ANSI/AAMI EC53:2013</b> ECG Trunk Cables and Patient Leadwires	Passed

## **9. Clinical tests performed that support a determination of substantial equivalence.**

Clinical testing for conformance with the requirements of ANSI/AAMI 81060-2:2013 and ISO80601-2-61: 2011 was completed to validate the clinical accuracy of the NIBP and SpO2 device functionality

## **10. Conclusions**

All the Performance Tests including non-clinical and clinical tests demonstrate that North-vision Elegant-1000 Series Multi-parameter Patient Monitors are as safe, as effective, and perform as well as the referenced legally marketed predicate device.