



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

February 26, 2016

Novian Health, Inc.  
% John Ziobro  
Principal Consultant  
Spectramedex, LLC  
117 W. South Street  
Oconomowoc, Wisconsin 53066

Re: K160392

Trade/Device Name: Novilase Laser Therapy System, Model LTS-2  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And  
In Dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: January 28, 2016  
Received: February 11, 2016

Dear John Ziobro:

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,

**Jennifer R. Stevenson -A**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K160392

Device Name

NOVILASE Laser Therapy System, Model LTS-2

Indications for Use (Describe)

The Novilase® Laser Therapy System (LTS-2) is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm, and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.

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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<b>NOVILASE® Laser Therapy System, Model LTS-2 Special 510(k) Summary</b>	<b>VOLUME 2</b>
	<b>SECTION 3</b>

### Special 510(k) Summary

1. Summary Date: 28 January 2016
2. Applicant Name: Novian Health, Inc.  
430 W Erie St Ste 500  
Chicago, IL 60654  
Ph: 312.266.7200  
Establishment Registration Number: 3009383334
3. Submission Correspondent: On behalf of Novian Health, Inc, the following consultant is assigned the responsibility of submission correspondence:  
John F. Ziobro  
Principal Consultant  
SpectraMedEx, LLC  
117 W. South Street  
Oconomowoc. WI 53066  
262.719.8922
4. Trade Name: Novilase® Laser Therapy System, Model LTS-2
5. Common Name: Laser Therapy System
6. Description: The Novilase Laser Therapy System (Model LTS-2) is a second-generation laser-based system that uses laser ablation to destroy tumors via a minimally-invasive procedure
7. Manufacturing Site: Biomedical Devices of Kansas  
(Hardware & Software) 1205 US 24/40 Highway, Suite100  
Tonganoxie, Kansas 66086  
913.845.3851  
Establishment Registration Number: 3007124677
8. Sterilization Site: Sterigenics  
1003 Lakeside Drive  
Lakeside, Illinois 60031  
847-263-3344  
Establishment Registration Number: 1450293
9. Classification Regulation, Class & Product Code & Panel:  
21 CFR 878.4810 Laser instrument, surgical, powered  
Class II  
Product Code: GEX  
Panel: General & Plastic Surgery
10. Reason for Special 510(k):  
Repackaging of the hardware to decrease size and weight and improve aesthetics, user interface modifications including the introduction of a touch-screen monitor.
11. Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:

**Quality, Risk Management & Process related Standards.**

CFR 21CFR820: Part 820 - QUALITY SYSTEM REGULATION,  
IEC 62304:2006 Medical device software - Software life cycle processes,  
ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes,  
ISO 14971:2012 Medical devices - Application of risk management to medical devices,

**Technical/ Product Specific Standards**

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ASTM D 4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems,  
 IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance,  
 IEC-60601-1-8:2010 Amendment 1 - 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, 2nd edition,  
 IEC 60601-2-22: Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment,  
 IEC 60825-1:2005 Safety of laser products - Part 1: Equipment classification and requirements, 2  
 ISO 11607:2003 Terminally Sterilized Medical Devices Package,  
 ISO 11607-1:2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems,  
 ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes,  
 21 CFR 1040.10-11: PART 1040 -- PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS,

**Labeling Standards**

EN 1041:2008 The system labelling shall comply with BS EN 1041:2008 Information supplied by the manufacturer of medical devices,  
 EN 556-1:2001 Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices,  
 ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement,

**Biocompatibility standards**

ISO 10993:2010 The parts of the system that come into contact with humans shall comply with AAMI / ANSI / ISO 10993:2010 (Biological evaluation of medical devices),

**Sterilization standards**

ISO 11137-1:2006 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices,  
 ISO 11137-2:2006 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose,  
 ISO 11137-3:2006 Sterilization of health care products -- Radiation -- Part 3: Guidance on dosimetric aspects, 12. Intended Use of Device

PRODUCT REQUIREMENTS DOCUMENT – Novilase Model LTS-2	
Intended use	The Novilase Laser Therapy System (LTS-2) has an intended use as a surgical instrument in the excision of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation.
Indication for Use	The Novilase® Laser Therapy System (LTS-2) is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm, and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.
Intended User	The Novilase LTS-2 user profile is a physician, radiologist or surgeon, with demonstrated experience in image-guided biopsy procedures.
Intended Use Environment	Medical treatment facilities such as hospitals, surgical centers, breast centers and physician offices with an ultrasound or x-ray imaging system, physical space to accommodate the Novilase LTS-2 unit and a "Laser in Use" sign on the procedure room door that meets laser safety requirements.
Targeted Patient Population	Females ages 15 and older with single or multiple fibroadenoma that do not exceed 2.0 cm in diameter and measure at least 0.5 cm away from the skin.



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PRODUCT REQUIREMENTS DOCUMENT – Novilase Model LTS-2	
Contraindications	None

13. Predicate Device(s): 510(k) Number: K070353  
 Manufacture: Kelsey, Inc. (Named changed to Novian Health, Inc. in 2007)  
 Trade Name: The Kelsey Interstitial Laser Therapy System (Name changed to the Novilase® Interstitial Laser Therapy System in 2007)  
 Product Code: GEX  
 Classification: 874.4810

14. Comparison to Predicates

The proposed device and the predicate device have the same/equivalent intended use, intended user, intended use environment and targeted patient population. Both devices use the same laser energy and treatment methodologies.

The main differences between Novilase Model LTS-2 Laser Therapy System and the Predicate Kelsey (now Novilase) Model ILT Laser Therapy System are the following:

- Repackaging of the hardware to decrease size and weight and improve aesthetics
- User interface modifications including the introduction of a touch-screen monitor
- The use of a newer/updated computer operating system.

The full Substantial Equivalence Comparison is contained in VOL\_003, Section\_002 Substantial Equivalence Comparison. The Substantial Equivalence Comparison Table 2-3.1 is included below for reader convenience.

15. Conclusions

Novian Health believes the proposed Novilase Laser Therapy System (Model LTS-2) and its predicate, the Kelsey Interstitial Laser Therapy System (Model ILT) are substantially equivalent in fundamental design and technology characteristics. Based on the predicate device comparison tables for the system under review, and the selected predicate, it is clear that these devices operate in an identical fashion, and there are no major deviations in design or functionality. The major differences in the systems pertain to repackaging the device to improve aesthetics and mobility, and improving the user-interface experience. In all cases, the devices are substantially equivalent and the same or better safety standards are met. In addition, no new issues pertaining to biocompatibility have been raised and therefore no clinical data was acquired.



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**Table 2-3.1 is a duplicate of Table 3-2.1 from VOL\_003, Section\_002 Substantial Equivalence Comparison document; it has been copied here for reader convenience. The table details the specifications of the device under review and compares it to the predicate device.**

Feature	Novilase® Laser Therapy System Model LTS-2 (Novilase System Under Review)	Kelsey Interstitial Laser Therapy System Model ILT (Cleared under K070353)	Substantial Equivalence Comments
<b>COMPARISON OF USES/INDICATIONS</b>			
Intended Use	The Novilase® Laser Therapy System (LTS-2) is intended for use as a surgical instrument in the excision of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation.	The Kelsey Interstitial Laser Therapy it is intended for use as a surgical instrument in the excision of external tumors and lesions, complete and partial resection of internal organs, treatment of tumors and lesions, skin incision and tissue dissection and ablation.	Both devices have the same intended use. Only the device name is updated. Therefore, Substantially Equivalent
Indication for Use Statement	The Novilase® Laser Therapy System (LTS-2) is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm, and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.	The Kelsey Interstitial Laser Therapy System is indicated for the treatment of fibroadenomas of the breast, with tumor sizes up to 20 mm, and for general surgery procedures including incision, excision and ablation of soft tissues; and coagulative necrosis and interstitial laser coagulation of soft tissues.	Both devices have the same indications for use statement. Only the device name is updated. Therefore, Substantially Equivalent  Note: the ongoing clinical study (NCT01478438, A Multicenter "Ablate and Resect" Study of Novilase® Interstitial Laser Therapy for the Ablation of Small Breast Cancers) is seeking to establish the use of the device on malignant tumors. This potential new indication for use is outside the scope of this submission. The subject device is indicated for the same uses as the predicate device.
Intended User	The Novilase® Laser Therapy System (LTS-2) user profile is a physician with experience in image-guided biopsy procedures.	The Kelsey Interstitial Laser Therapy user profile is a physician with experience in image-guided biopsy procedures.	Both devices have the same intended user profile. Therefore, Substantially Equivalent
Intended Use Environment	Medical treatment facilities such as hospitals, surgical centers, breast centers and physician offices with an ultrasound or x-ray imaging system, physical space to accommodate the Novilase LTS-2 unit and a "Laser in Use" sign on the procedure room door that meets laser safety requirements.	Medical treatment facilities such as hospitals, surgical centers, breast centers and physician offices with an ultrasound or x-ray imaging system, physical space to accommodate the device and a "Laser in Use" sign on the procedure room door that meets laser safety requirements.	Both devices have the same intended use environments. Therefore, Substantially Equivalent
Target Patient Population	Females ages 15 and older with single or multiple fibroadenoma that do not exceed 2.0 cm in diameter and measure at least 0.5 cm away from the skin.	Females ages 15 and older with single or multiple fibroadenoma that do not exceed 2.0 cm in diameter and measure at least 0.5 cm away from the skin.	Identical patient populations. Therefore, Substantially Equivalent
Contraindications	None.	The predicate submission did not contain any contraindications	Neither the predicate nor the proposed device have any contraindications. Therefore, Substantially Equivalent
<b>COMPARISON OF SYSTEM CONFIGURATIONS</b>			
System-Level Components	LTS System consisting of: <ul style="list-style-type: none"> <li>• Thermistor controller and associated hardware.</li> <li>• Laser diode source, 1-8 watts, 805 nominal nanometer wavelength.</li> <li>• Personal computer running Windows 7, or better, including monitor, keyboard, touch-screen display) and mouse.</li> <li>• Power distribution unit with user accessible master power</li> </ul>	ILT System consisting of: <ul style="list-style-type: none"> <li>• Thermistor controller and associated hardware.</li> <li>• Laser diode source, 1-8 watts, 805 nominal nanometer wavelength.</li> <li>• Personal computer running Windows XP with Service Pack 2 or better, including monitor, keyboard and mouse.</li> <li>• Power distribution unit with user accessible master power</li> </ul>	The differences between the subject device and the predicate device are discussed in further detail in Table 3-2.2 below. Some components were updated to reflect differences in the operating system (Windows 7), ergonomics (touch screen), and dimensions (cart). The predicate device has a uninterruptible power supply (UPS) while the



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Feature	Novilase® Laser Therapy System Model LTS-2 (Novilase System Under Review)	Kelsey Interstitial Laser Therapy System Model ILT (Cleared under K070353)	Substantial Equivalence Comments
	switch. <ul style="list-style-type: none"> <li>• Isolation transformer.</li> <li>• Thermal temperature to digital converter.</li> <li>• Lightweight storage cart.</li> </ul>	switch. <ul style="list-style-type: none"> <li>• Uninterruptible power supply (UPS).</li> <li>• Isolation transformer.</li> <li>• Thermal temperature to digital converter.</li> <li>• Storage cart.</li> </ul>	proposed device does not. A technical comparison of the components, combined with the verification and validation testing described in Volume 4, Section 1 demonstrate that the modifications do not raise new questions of safety or effectiveness and the device continues to meet its specifications. Therefore, Substantially Equivalent
Additional Required Components	Infusion pump capable of accurately dispensing 60 cc syringes of saline at variable flow rates to 1 cc per minute, continuously adjustable, including bolus function.	Infusion pump capable of accurately dispensing 60 cc syringes of saline at variable flow rates to 1 cc per minute, continuously adjustable, including bolus function.	Both devices use the same infusion pump. Therefore, Substantially Equivalent
Reusable Accessories (included with unit; may be available for sale separately)	<ul style="list-style-type: none"> <li>• Connector box</li> <li>• Umbilical cable, (contains the wires and optical fiber running between the connector box and the LTS cart).</li> <li>• Laser glasses</li> <li>• USB thumb drive (for data storage)</li> <li>• One color-coded adaptor for the laser probe</li> <li>• One color-coded adapter for the thermal probe</li> </ul>	<ul style="list-style-type: none"> <li>• Connector box</li> <li>• Umbilical cable, (contains the wires and optical fiber running between the connector box and the ILT cart).</li> <li>• Laser glasses (These are included with shipments, but were not described in the original submission.</li> <li>• USB thumb drive (This is included with shipments, but it was described in the original submission.)</li> </ul>	Both devices use the same reusable accessories. Two color-coded and independently non-sterile adaptors (called “patch cords” by the Company) are provided by the company and shipped separately from the main kit. Their purpose is to help the end-user better differentiate the probes when connecting them to the main unit and to serve as receptacle adapters to accommodate predicate probe connector plugs. For additional information, please refer to table 3-2.2 below. Therefore, Substantially Equivalent
Disposable Accessories	A Gamma-sterilized Laser Probe Kit, consisting of: <ul style="list-style-type: none"> <li>• One disposable laser probe, hollow 14 gauge 304 stainless steel with one attached thermistor.</li> <li>• One disposable thermal probe, solid 14 gauge 304 stainless steel with five embedded thermistors</li> <li>• One probe holder</li> <li>• One hemostasis valve</li> <li>•</li> </ul>	A Gamma-sterilized Laser Probe Kit, consisting of: <ul style="list-style-type: none"> <li>• One disposable laser probe, hollow 14 gauge 304 stainless steel with one attached thermistor.</li> <li>• One disposable thermal probe, solid 14 gauge 304 stainless steel with five embedded thermistors</li> <li>• One probe holder</li> <li>• One hemostasis valve</li> </ul>	The operating principles, materials and sterilization processes used for the proposed kit are identical to the predicate. Therefore, Substantially Equivalent
<b>COMPARISON OF INPUT ENERGY</b>			
Power Source	Single phase 110/220 VAC, 2A 50 or 60 Hz	Single phase 110/220 VAC, 2A 50 or 60 Hz	Identical specifications. Therefore, Substantially Equivalent
<b>COMPARISON OF OUTPUT ENERGY (Principle of Operation) &amp; PERFORMANCE SPECIFICATIONS</b>			
Device Type	GaAIAs Laser Diode	GaAIAs Laser Diode	Identical specifications. Therefore, Substantially Equivalent
Laser Safety Class	IV	IV	
Wavelength	805 nm ± 15 nm	805 nm ± 15 nm	
Power at Tissue	1 – 8 watts	1 – 8 watts	
Treatment Mode	Continuous operation	Continuous operation	
Optical Output	Multimode	Multimode	
Calibration	Internal, automatic, ± 20%	Internal, automatic, ± 20%	
Delivery System	600 µm core diameter	600 µm core diameter	



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Feature	Novilase® Laser Therapy System Model LTS-2 (Novilase System Under Review)	Kelsey Interstitial Laser Therapy System Model ILT (Cleared under K070353)	Substantial Equivalence Comments
Cooling System	Ambient Air	Ambient Air	
Temperature sensing range	0°C - 105°C	0°C - 105°C	
<b>COMPARISON OF PATIENT CONTACT MECHANISMS &amp; MATERIALS</b>			
Patient Contact/Interface Materials	14 gauge, 0.010” thick wall, 304 stainless steel pointed, closed-end trocar laser and thermal probes with Loctite 3321 adhesive and Cobalt Polymers U2-110-CLR shrink tubing and quartz fiber	14 gauge, 0.010” thick wall, 304 stainless steel pointed, closed-end trocar laser and thermal probes with Loctite 3321 adhesive and Cobalt Polymers U2-110-CLR shrink tubing and quartz fiber	There have been no changes to the patient contacting materials or method of manufacture since previous clearance. Therefore, Substantially Equivalent
Fiber optic length	2.3m umbilical fiber	0.25 m internal fiber + 4.0 m umbilical fiber	Overall fiber optic length was reduced. Testing shows no effect on performance, safety or efficacy For additional information, please refer to Table 3-2.2 below. Therefore, Substantially Equivalent
Fiber optic length (patient contact)	1.0 m	1.0 m	Identical fiber optic length making patient contact. Therefore, Substantially Equivalent
<b>COMPARISON OF COMPUTER INTERFACE &amp; ERGONOMICS/HUMAN FACTORS</b>			
Computer Specifications	<ul style="list-style-type: none"> <li>• The unit has the following minimum required input/output ports: 1x USB 2.0: 1x Serial; Integrated audio and speakers; video display</li> <li>• Input power of 100V-240V AC</li> <li>• 4GB of memory</li> <li>• Integrated graphics card.</li> <li>• 10 GB HDD or greater</li> <li>• Intel compatible CPU rated for use compatibility with Windows XP or better</li> </ul>	Not specified	Both proposed and predicate device require the use of a computer. The specifications for the proposed device are provided. The specifications for the predicate device’s computer were not included in the previous submission. The V&V testing described in VOL_4/SEC_1 demonstrates that when used with the specified computer, the device continues to meet its performance specifications. Therefore, Substantially Equivalent
Operating System	Windows 7	Windows XP with service pack 2 or better	PC Environment updated per new standard operating systems; As emulated, identical to predicate. Therefore, Substantially Equivalent
User Input Mechanism	Touch Screen and/or mouse & keyboard	Keyboard	Increased input functionality by adding touch screen functionality. Therefore, Substantially Equivalent
Display	15” display size monitor	15” display size monitor	Identical specification. Therefore, Substantially Equivalent
External Media Storage	USB	USB	Identical specification. Therefore, Substantially Equivalent
Alarms	Software prompts, warnings and audible alarm indications	Software prompts, warnings and audible alarm indications	The software provides and operates with the same set of alarms and warnings. No new alarms or alerts have been added. Therefore, Substantially Equivalent
<b>COMPARISON OF DIMENSIONAL SPECIFICATIONS</b>			



**NOVILASE®**  
**Laser Therapy System, Model LTS-2**  
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Feature	Novilase® Laser Therapy System Model LTS-2 (Novilase System Under Review)	Kelsey Interstitial Laser Therapy System Model ILT (Cleared under K070353)	Substantial Equivalence Comments
Dimensions	21D x 18W x 61H (inches). Height is adjustable	32D x 24W x 51H (inches)	The new device is slightly taller in its maximal height. This does not have an impact on the use environment. Therefore, Substantially Equivalent
Weight	180 lbs	250 lbs	The new unit is lighter in weight by 70 lbs. Increased mobility. This does not have an impact on the use environment or intended user. Therefore, Substantially Equivalent
Caster Diameter	4 inches	3 inches	The larger diameter wheels add to the mobility and stability of the device. This does not have an impact on the use environment or intended user. Therefore, Substantially Equivalent
<b>COMPARISON OF ENVIRONMENT SPECIFICATIONS</b>			
Operating Environment	Operating temperature range: 15°C to 30°C Operating humidity: 10-90% non-condensing humidity Operating pressure: Sea-level to 2,000m	10° - 40° C, 0 - 80% RH, decreasing linearly to 50% RH at 40° C, sea level to 2,000 meters (no protection against ingress of moisture) Drip-proof	The specifications for the operating environment have been tightened for increased control and environmental consistency. The V&V testing described in VOL_4/SEC_1 demonstrates that the device meets its performance specifications when used in these operating environment specifications. This does not raise new questions of safety or effectiveness. Therefore, Substantially Equivalent
Storage Environment	Transportation and storage temperature range: -10°C to 40°C Transportation and storage humidity range: Non-condensing humidity Transportation and storage pressure: Sea-level to 2,000m	Not specified	The storage environment specifications were not described in the predicate submission. However, they do not have an impact on device performance and do not raise new questions of safety or effectiveness. Therefore, Substantially Equivalent

**Table 2-3.1 Substantial Equivalence Comparison Table**