April 27, 2018

Conavi Medical Inc.
Sam Mostafavi
Director of Regulatory
293 Lesmill Road
North York, ON, Canada M3B 2V1

Re: K172258
Trade/Device Name: Novasight Hybrid System
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, NQQ, IYO
Dated: March 24, 2018
Received: March 26, 2018

Dear Sam Mostafavi:

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.

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.

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,

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)*
K172258

Device Name
Novasight Hybrid System

Indications for Use *(Describe)*

The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

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

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K172258

Applicant Information:

Date Prepared:	March 16, 2018
Name:	Conavi Medical Inc.
Address:	293 Lesmill Road North York, ON, Canada M3B 2V1
Contact Person:	Sam Mostafavi Sam@Conavi.com
Mobile Number:	(650) 670-6972
Office Number:	(416) 483-0100
Facsimile Number:	(416) 483-0101

Device Information:

Trade/Proprietary Name:	Novasight Hybrid System
Common Name:	Novasight Hybrid System
Classification Name:	Diagnostic Intravascular Catheters, 21 CFR 870.1200 Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560
Product Code	OBJ, NQQ, IYO
Class:	Class II
Panel:	Division of Cardiovascular Devices

Predicate Device:

Primary:

- Volcano Corporation, Revolution™ 45 MHz Rotational Imaging Catheter K050995

Secondary:

- Lightlab Imaging, Ilumien Optis, Dragonfly Optis Imaging Catheter K141453
- Volcano s5s5i Series Intravascular Imaging and Pressure Systems K071554

Device Description

The Novasight™ Hybrid System is intended for real-time, minimally-invasive guidance of transluminal interventional procedures. The system provides image information of coronary vessel anatomic features, spatial relationships of other devices within the coronary

arteries, and intra-procedural complications such as perforation.

The system is comprised of a catheter and a cart based console. The console includes the Acquisition and Display Module (ADM) for image acquisition, display and manipulation as well as the Patient Interface Module (PIM) which the catheter connects to. The ADM has two monitors to allow for ease of image view and review for both the technologist and the physician users. The technologist user is able to control the system software via an easy to use interface using multiple methods of input including a trackpad, keyboard and/or a touch screen. Casters on the ADM allow easy movement of the system throughout a cath lab which can have a small footprint as well as small obstacles to cross. The PIM has a user interface for the physician to have control over the acquisition. It is also compact such that it can be moved and handled by an able-bodied user. The system includes software build version 2.0 (2.0.6607.31062).

The catheter is a 3Fr single use, sterile device, which is able to perform transluminal ultrasound and optical coherence tomography imaging of adults. The catheter is capable of real-time 2D side viewing ultrasound and optical imaging acquired simultaneously providing precisely co-registered images with the ability to produce rapidly post processed rendered longitudinal images of the vessel. The imaging system is able to resolve features within coronary arteries such as healthy tissue and stent struts. The physician user has the ability to manually position the imaging sensor as well as perform pullback (automatically or manually trigger) for defined regions of interest.

Indications for Use

The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

Functional and Technological Comparison

Tables 1 and 2 below include functional and technological comparison between Conavi Medical Novasight Hybrid System and FDA cleared marketed systems.

Table 1 provides functional and technological comparison of Conavi Medical Novasight Hybrid Catheter to Volcano Corporation, Revolution™ 45 MHz Rotational Imaging Catheter (K050995), and Lightlab Imaging, Ilumien Optis, Dragonfly Optis Imaging Catheter (K141453)

Table 2 provides functional and technological comparison of Conavi Medical Novasight Hybrid System (Console and PIM) to the Volcano s5s5i Series Intravascular Imaging and Pressure Systems (K071554).

Table-1: Catheter substantial equivalency comparison

Component	Subject Device	Predicate Devices		Comments
	Conavi Novasight Hybrid Catheter (K172258)	**Volcano Revolution™ 45 MHz Rotational Imaging Catheter (K050995)**	**Lightlab Ilumien Optis, Dragonfly Optis Imaging Catheter (K141453)**	
Classification	Class II	Class II	Class II	*Same as predicate devices*
Regulation Name	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	Diagnostic Intravascular Catheter	*Same as predicate devices*
Product code	OBJ, NQQ	OBJ	NQQ	*Same as predicate devices*
Catheter type	Intravascular Imaging Catheter	IVUS Imaging Catheter	Intravascular OCT Catheter	*Similar to predicate devices*
Clinical data	No clinical study is included in the submission. Determination of substantial equivalence Performance is based on an assessment of non-clinical data.	No clinical testing is mentioned in the performance data.	No clinical testing is mentioned in the performance data. Determination of substantial equivalence performance is based on an assessment of non-clinical data.	*Same as predicate devices*
Performance data	Bench-top evaluations, risk analysis, packaging validation, biocompatibility, electrical safety, acoustic output, and pre-clinical	In accordance with design controls including risk analysis, and biocompatibility test.	Electrical safety, software verification and validation, bench test, and pre-clinical animal testing.	*Similar to predicate devices*

Intended use	The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	The Revolution™ 45 MHz Rotational IVUS Imaging Catheter is intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.	The ILUMIEN OPTIS with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.	*Similar to the predicate devices*
Crossing profile in imaging window (Nominal)	2.8F	3.2F	2.7F	*Similar to predicate devices*

Working Length	149cm	135cm	135cm	*Similar to predicate devices*
Compatible Guidewire	0.014”	0.014”	0.014”	*Similar to predicate devices*
Rotational speed	30-100 RPS	30 RPS	180 RPS	*Similar to predicate devices*
Pullback length	10cm	15cm	7.5cm	*Similar to predicate devices*
Pullback speed	0.5mm/s to 25mm/s	0.5 to 1mm/s	36mm/s	*Similar to predicate devices*
Catheter preparation	Saline flush	Saline flush	Contrast flush	*Similar to predicate devices*
Minimum Guide Catheter	>=6F	>=6F	>=6F	*Same as predicate devices*
Imaging energy	Ultrasound/ Optical Coherence Tomography (IVUS/OCT) Imaging	Ultrasound Imaging	Optical Coherence Tomography (OCT) Imaging	*Similar to predicate devices*
Catheter configuration	Single ultrasound and optical imaging element, mechanically rotated.	Single ultrasound imaging element, mechanically rotated.	Single optical imaging element, mechanically rotated.	*Similar to predicate devices*
Ultrasound imaging frequency	40MHz	45 MHz	N/A	*Similar to predicate device*
Optical wavelength	1310nm	N/A	1310nm	*Same as predicate device*
Proximal end configuration	Single connector, mechanical snap into motor drive unit (referred to as PIM).	Single connector, mechanical snap into motor drive unit (referred to as PIM).	Single connector, mechanical snap into motor drive unit (referred to as DOC).	*Same as predicate devices*
Acoustic output	Max Pressure: 2.96 MPa	Max Pressure: 1.9 MPa	N/A	*Similar to predicate device*
	MI: 0.54	MI: 0.281	N/A	*Similar to predicate device*
Acoustic testing	IEC 60601-2-37:2007 and equivalent analysis to NEMA UD-2 performance	IEC 60601-2-37	N/A	

Sterilization	ISO 11137-2 ISO 11137-1-3	ISO 11737	ISO 11737	*Similar to predicate devices*
Imaging Modes	B-Mode IVUS B-Mode OCT	B-Mode IVUS	B-Mode OCT	*Similar to predicate devices*
Biocompatibility	ISO 10993, Externally Communicating Device, Circulating Blood category	ISO 10993, Externally Communicating Device, Circulating Blood category.	ISO 10993, Externally Communicating Device, Circulating Blood category	*Similar to predicate devices*
Catheter construction	Biocompatible Thermopolymer sheath delivered over monorail	Biocompatible Thermopolymer sheath delivered over monorail	Biocompatible Thermopolymer sheath delivered over monorail	*Same as predicate derives*
Re-usability	Single use	Single use	Single use	*Same as predicate derives*

Table-2: Console Comparison Table

Component	Subject Device: Conavi Novasight Hybrid System (K172258)	Lightlab Ilumien Optis, Dragonfly Optis Imaging Catheter (K141453)	Volcano s5s5i Series Intravascular Imaging and Pressure Systems (K071554)	Comment
Configuration	Mobile cart with braking system	Mobile cart with braking system	Mobile cart with braking system	*Same as predicate devices*
Product Code	NQQ, IYO	NQQ	IYO	*Same as predicate devices*
Input	Touchscreen, touchpad, and keyboard	Keyboard and mouse	Keyboard and trackball	*Similar to predicate devices*
Display	Dedicated image display monitor, images also displayed on Touchscreen	Dual monitor configuration	single monitor configuration	*Similar to predicate devices*

Intended use	The Novasight Hybrid System is intended for intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.	The ILUMIEN OPTIS with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The ILUMIEN OPTIS will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.	The Volcano s5/s5i Series Intravascular Imaging and Pressure System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures. ChromaFlo® is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion. VH IVUS is intended to be used in conjunction with imaging catheters during diagnostic ultrasound imaging of the peripheral and coronary vasculature. The Volcano VH IVUS System is intended to semi-automatically visualize boundary features and perform spectral analysis of RF ultrasound signals of vascular features that the user may wish to examine more closely during routine diagnostic ultrasound imaging examinations. The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures. Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature. As an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures. The pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.	*Similar to predicate devices*

Data storage	DICOM and native format	DICOM and native format	DICOM and native format	*Same as predicate device*
Footprint	502 x 502mm (centre to centre distance of casters)	610 x 710 mm (total footprint)	559 x 838 mm (total footprint)	*Similar to predicate devices*
Electrical safety	IEC 60601-1 3rd edition IEC 60601-1-2:2007 IEC 60601-2-37:2007 IEC 60601-2-18:2009 IEC 60825-1:2014	IEC 60601-1:2005+A1:2012 EN60601-1-2:2007 60601-1-14 IEC 60825-1 2nd Ed. 2007 IEC 60601-2-18:2009	IEC 60601-1:2005, Ed 2 IEC 60601-1-1:2000 IEC 60601-1-2:2007 IEC 60601-2-34:2000-10 Ed 2 IEC 60601-2-37:2007 Ed 2	*Similar to predicate devices*
Sterile barrier interface	Motor Drive Unit (referred to as Patient Interface Module) encapsulated in single use disposable sterile bag	Motor Drive Unit (referred to as Drive-motor and Optical Controller)	Motor Drive Unit (referred to as Patient Interface Module) encapsulated in single use disposable sterile bag	*Same as predicate devices*
Max optical output power (measured at Motor Drive unit)	23.3mW	22.6mW	Not applicable	*Similar to predicate*

System: Novasight Hybrid System
Transducer: Novasight Hybrid Catheter
Intended Use: Visualization of human anatomy by means of ultrasound imaging:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)	N						
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							

Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

For evidence of system compliance to guidance provided in Guidance for Industry and FDA Staff - Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, please refer to EXT-023, Novasight Hybrid System Compliance to FDA Guidance for Diagnostic Ultrasound Systems and Transducers.

Scanning Operating Mode: IVUS ONLY

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.54	0.12		0.19		0.19
Index component value				sc: 0.12 ns: N/A	sc: 0.12 ns: N/A	sc: 0.19 ns: N/A	sc: 0.12 ns: N/A	
Acoustic Parameters	$p_{r.\alpha}$ at z_{MI}	[MPa]	2.96					
	P	[mW]		0.73		0.73		0.73
	P_{1x1}	[mW]		0.73	0.73	0.73	0.73	
	z_s	[cm]			0.18			
	z_b	[cm]					0.18	
	z_{MI}	[cm]	0.18					
	$z_{pii,\alpha}$	[cm]	0.18					
	f_{awf}	[MHz]	31.25 – 45.00					
Other Information	prr	[KHz]	24.39					
	srr	[Hz]	30 or 100					
	n_{pps}		1					
	$I_{pa,\alpha}$ @ $z_{pii,\alpha}$	[W/cm²]	65.95					
	$I_{spta,\alpha}$ @ $z_{pii,\alpha}$ or $z_{sii,\alpha}$	[mW/cm²]	23.58					
	I_{spta} @ z_{pii} or z_{sii}	[mW/cm²]	36.42					
	p_r @ z_{pii}	[MPa]	3.19					
Operating Control	Depth Boost		On					
	Frequency		40 MHz					

Scanning Operating Mode: IVUS + OCT

Index Label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.54	0.24		0.36		0.36
Index component value				sc: 0.24 ns: N/A	sc: 0.24 ns: N/A	sc: 0.36 ns: N/A	sc: 0.24 ns: N/A	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	[MPa]	2.96					
	P	[mW]		1.42		1.42		1.42
	P_{1x1}	[mW]		1.42	1.42	1.42	1.42	
	z_s	[cm]			0.18			
	z_b	[cm]					0.18	
	z_{MI}	[cm]	0.18					
	$z_{pii,\alpha}$	[cm]	0.18					
	f_{awf}	[MHz]	31.25 – 45.00					
Other Information	prr	[KHz]	47.62					
	srr	[Hz]	30 or 100					
	n_{pps}		1					
	$I_{pa,\alpha}$ @ $z_{pii,\alpha}$	[W/cm²]	129.2					
	$I_{spta,\alpha}$ @ $z_{pii,\alpha}$	[mW/cm²]	46.19					
	I_{spta} @ z_{pii}	[mW/cm²]	71.34					
	p_r @ z_{pii}	[MPa]	3.19					
Operating Control	Depth Boost		On					
	Frequency		40 MHz					

f_{awf}	ACOUSTIC WORKING FREQUENCY
$I_{pa,\alpha}$	ATTENUATED PULSE-AVERAGE INTENSITY
I_{spta}	SPATIAL-PEAK, TEMPORAL-AVERAGE INTENSITY (in Water)
$I_{spta,\alpha}$	ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY
MI	MECHANICAL INDEX
P	OUTPUT POWER (in Water)
P_{1x1}	BOUNDED-SQUARE OUTPUT POWER (in Water per 1cm x 1cm)
$p_{r,\alpha}$	ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE
p_r	PEAK-RAREFACTIONAL ACOUSTIC PRESSURE (in water)
n_{pps}	NUMBER OF PULSES PER ULTRASONIC SCAN LINE
p_{rr}	PULSE REPETITION RATE
s_{rr}	SCAN REPETITION RATE
TIB	BONE THERMAL INDEX
TIC	CRANIAL-BONE THERMAL INDEX
TIS	SOFT-TISSUE THERMAL INDEX
sc	SCANNING MODE
ns	NON-SCANNING MODE
z_b	DEPTH FOR *TIB*
z_{pii}	DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL
z_{MI}	DEPTH FOR MECHANICAL INDEX
$z_{pii,\alpha}$	DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL
z_s	DEPTH FOR *TIS*

Non Clinical Performance Testing

Verification and validation test were performed in accordance with the following standards, and test results confirm that results demonstrate that Novasight Hybrid System demonstrate as intended meeting the applicable requirements. Standards include:

1. IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
2. IEC 60601-1-2:2007 (Ed3.0), Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility.
3. IEC 60601-1-6:2013, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
4. IEC 60825-1:2014 (Third Ed), Safety of laser products – Part 1: Equipment classification and requirements
5. IEC 60601-2-18:2009 (Third Ed) for use in conjunction with IEC 60601-1:2005, Medical Electrical Equipment - Part 2-18: Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment.
6. IEC 60601-2-37:2007 & A1:2015, for use in conjunction with IEC 60601-1:2005, Medical Electrical Equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
7. IEC 61161:2013, Ultrasonic - Power measurement - Radiation force balances and performance requirements.
8. IEC 62127-1:2013, Ultrasonic - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz
9. IEC 62359:2010, Ultrasonic - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.
10. ISO 11607-1:2006, Packaging for terminally sterilized medical device. Part 1: requirements for materials, sterile barrier systems and packaging systems (2006 Amendment 1, 2014).
11. ISO 11137-1:2006, Sterilization of healthcare products – Radiation (Gamma & E-Beam Sterilization for Medical Devices).
12. ANSI/AAMI/ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
13. ISO 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.
14. ISO 14971:2012, Medical Devices - Risk Management Process
15. ANSI/AAMI/IEC 62304:2006, Software development lifecycle

Conclusion:

Conavi Novasight Hybrid System, the subject device, and predicate devices have very similar intended use, principles of operational and technological characteristics. The subject device and predicate devices are intended for intravascular imaging use. Minor technological differences do not raise any new safety and effectiveness risk or concerns. Additionally, non-clinical test results confirm that Novasight Hybrid System meets the intended use and the requirements of applicable standards. Therefore, it is the conclusion of Conavi Medical that Conavi Novasight Hybrid System is substantially equivalent to the cited predicate devices.