December 17, 2020

Philips Medical System Nederland B.V.
Gert De Vries
Senior Regulatory Affairs Manager
Veenpluis 4-6
Best, Noord-Brabant 5684 PC
Netherlands

Re: K201081
Trade/Device Name: AltaTrack equipment, AltaTrack Guidewire, AltaTrack Catheter
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: Class II
Product Code: DQK, DQX, DQO
Dated: November 10, 2020
Received: November 16, 2020

Dear Gert De Vries:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carmen Gacchina Johnson, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support, Structural & Vascular Devices
Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K201081

Device Name
AltaTrack equipment;
AltaTrack Guidewire;
AltaTrack Catheter

Indications for Use *(Describe)*
The AltaTrack equipment is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Catheter and/or AltaTrack Guidewire during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real time of an AltaTrack Catheter and/or AltaTrack Guidewire.

The AltaTrack Guidewire is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter during navigation in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

The AltaTrack Catheter is an angiographic catheter with Fiber Optic RealShape (FORS) technology, intended to deliver radiopaque media or lead a guidewire in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

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 510(k) summary has been prepared in accordance with 21 CFR 807.92.

510(k) Number: K201081

SUBMITTER INFORMATION

Submitted by:
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Date Prepared: April 16 2020

DEVICE NAME

Device Trade Name:	AltaTrack equipment
Common Name:	Computer, diagnostic, programmable
Classification Name:	Programmable diagnostic computer, 21 CFR 870.1425: Class II Product code DQK

Device Trade Name:	AltaTrack Guidewire
Common Name:	Wire, guide, catheter
Classification Name:	Catheter guide wire, 21 CFR 870.1330: Class II Product code DQX

Device Trade Name:	AltaTrack Catheter
Common Name:	Catheter, intravascular, diagnostic
Classification Name:	Diagnostic intravascular catheter, 21 CFR 870.1200: Class II Product code DQO

PREDICATE DEVICES

AltaTrack equipment	MediGuide™ Technology System Version 17.0 (K162643)
AltaTrack Guidewire	Radifocus Glidewire® (K152740)
AltaTrack Catheter	Radifocus® Optitorque™ Angiographic Catheter (K150232)

DEVICE DESCRIPTION

AltaTrack equipment	The AltaTrack equipment is a visualization device with Fiber Optic RealShape (FORS) technology. Its function is to create a 3D image in real time of an AltaTrack Guidewire and/or AltaTrack Catheter and overlay it on real-time or pre-recorded 2D fluoroscopy images and/or on pre-operative 3D CT images, if available. The AltaTrack equipment comprises software and hardware components (such as lasers, optical components, computer hardware, electrical and optical cabling), and a single-use, sterile, detachable component.

AltaTrack Guidewire	The AltaTrack Guidewire is a single-use, sterile, hydrophilic guidewire with FORS technology. The primary function of the AltaTrack Guidewire is to direct an AltaTrack Catheter or other compatible catheter to a desired anatomical location. It can be visualized in 3D in real time by the AltaTrack equipment using FORS technology.
AltaTrack Catheter	The AltaTrack Catheter is a single-use, sterile, angiographic catheter with FORS technology. Its primary function is to deliver radiopaque media or lead an AltaTrack Guidewire or other compatible guidewire to a desired anatomical location. It can be visualized in 3D in real time by the AltaTrack equipment using FORS technology.

INDICATIONS FOR USE

AltaTrack equipment	The AltaTrack equipment is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Catheter and/or AltaTrack Guidewire during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real time of an AltaTrack Catheter and/or AltaTrack Guidewire.
AltaTrack Guidewire	The AltaTrack Guidewire is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter during navigation in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.
AltaTrack Catheter	The AltaTrack Catheter is an angiographic catheter with Fiber Optic RealShape (FORS) technology, intended to deliver radiopaque media or lead a guidewire in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.

TECHNOLOGICAL CHARACTERISTICS

AltaTrack equipment	The proposed AltaTrack equipment and the predicate MediGuide™ Technology System Version 17.0 (K162643) have fundamentally the same intended use. The AltaTrack equipment and the predicate MediGuide™ Technology System both enable real time positioning and navigation for (minimally) invasive device(s) in peripheral endovascular interventions. Both support their own technology equipped guidewire(s) and catheter(s). The tracking technology deployed with AltaTrack equipment is Fiber Optic RealShape (FORS) technology to visualize the shape of the invasive devices over their entire length. The predicate device deploys Electro-magnetic (E/M) sensing technology, which is typically used to visualize the distal tip of the invasive devices. The technological difference does not raise any new questions regarding safety and effectiveness Table below provides a device comparison between the subject AltaTrack equipment and the predicate MediGuide™ Technology System Version 17.0 (K162643).

Attribute	Proposed device	Predicate device
Name	AltaTrack equipment	MediGuide™ Technology System Version 17.0 (K162643)
Manufacturer	Philips Medical Systems	St. Jude Medical
Product code	DQK	DQK
Classification	II	II
Indications for use	The AltaTrack equipment is an imaging device with Fiber Optic RealShape (FORS) technology intended to aid the positioning and navigation of a connected AltaTrack Catheter and/or AltaTrack Guidewire during endovascular procedures of the peripheral, aortic and aortic side branch vasculature, by creating a 3D image in real time of an AltaTrack Catheter and/or AltaTrack Guidewire.	The MediGuide™ Technology system is intended for the evaluation of vascular and cardiac anatomy. It is intended to enable real time tip positioning and navigation of a MediGuide Enabled™ / Sensor Enabled™ (equipped with a magnetic sensor) invasive device used in vascular or cardiac interventions in the Cath Lab environment, on both live fluoroscopy or recorded background. The System is indicated for use as an adjunct to fluoroscopy.
Patient population	Patients eligible for endovascular procedures.	Patients eligible for vascular or cardiac interventional procedures.
Application area	Peripheral, aortic and aortic side branch	Vascular or cardiac interventions
Clinical environment	In the control room and in the exam room of an interventional suite or hybrid operating room.	In the control room and in the exam room of an interventional suite or hybrid operating room.
Adjunct devices	Used in conjunction with fluoroscopy	Used in conjunction with fluoroscopy
Summary of device description	AltaTrack equipment consists of hardware and software elements, which are installed in conjunction with an interventional X-ray system. The interventional system continues to perform safely and effectively per its intended use, while enabling enhanced anatomical context visualization and invasive device visualization.	MediGuide™ Technology System consists of hardware and software elements, which are installed in conjunction with the existing fluoroscopy Imaging System in a Cath Lab. The conventional fluoroscopy Imaging System, equipped with MediGuide™ Technology elements, continues to perform safely and effectively per its intended use as fluoroscopic imaging device, while enabling device tracking and enhanced visualization tools supplied by MediGuide™ Technology capabilities.
Technology for invasive device visualization	Fiber-Optic RealShape (FORS) technology.	Electro-magnetic (E/M) sensing technology.
Tracked invasive	AltaTrack Catheter AltaTrack Guidewire	Variety of MediGuide Enabled™/Sensor

device		Enabled™ catheters, guidewires

AltaTrack Guidewire

The AltaTrack Guidewire and the predicate Radiofocus Glidewire (K152740) have the same intended use. The AltaTrack Guidewire and the predicate device are both designed for use in peripheral endovascular procedures, with similarities including mechanical handling properties, radiopacity, sterilization method and packaging design. Contrary to the predicate device, the AltaTrack Guidewire contains a fiber-optic sensor, which enables it to be visualized using FORS technology. The technological difference does not raise any new questions regarding safety and effectiveness.

The table below provides a device comparison between the subject AltaTrack Guidewire and the predicate Radifocus Glidewire (K152740).

Attribute	Proposed device	Predicate device
Name	AltaTrack Guidewire	Radifocus Glidewire (K152740)
Manufacturer	Philips Medical Systems	Terumo Corporation
Product code	DQX	DQX
Classification	II	II
Indications for Use	The AltaTrack Guidewire is an angiographic guidewire with Fiber Optic RealShape (FORS) technology, intended to direct a catheter during navigation in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.	The Glidewire is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.
Site in the body	Peripheral, aortic and aortic side branch vasculature	Peripheral vasculature
Operation principle	Manual	Manual
Specifications	Wire diameter: 0.035”	Wire diameter: 0.035”
	Device length (in-body section): 120 cm	Device length: 260, 300, 350, 400, and 450 cm. Note that K152740 extends the working length of its predicate (K863138), which has lengths from 30-300 cm.
	Length of the flexible part of the distal tip: 3 cm	Lengths of the flexible part of the distal tip: 3 and 5 cm.
	Distal tip shape: angled	Distal tip shape: straight and angled
	Shaft configuration: standard	Shaft configurations: standard and stiff
Packaging Configuration	Individual package, unit box, shipping carton.	Individual package, unit box, shipping carton.
Sterilization Method	Ethylene Oxide (EO)	EO

AltaTrack Catheter

The AltaTrack Catheter and the predicate Radifocus® Optitorque™ Angiographic Catheter (K150232) have fundamentally the same intended use. Both the AltaTrack

Catheter and the predicate device are designed for use in peripheral endovascular procedures with similarities including mechanical handling properties, radiopacity, sterilization method and packaging design.
Contrary to the predicate device, the AltaTrack Catheter contains a fiber-optic sensor, which enables it to be visualized using FORS technology. The technological difference does not raise any new questions regarding safety and effectiveness.

The table below provides a device comparison between the subject AltaTrack Catheter and the predicate Radifocus® Optitorque™ Angiographic Catheter (K150232).

Attribute	Proposed device	Predicate device
Name	AltaTrack Catheter	Radifocus® Optitorque™ Angiographic Catheter
Manufacturer	Philips Medical Systems	Terumo Corporation
Product code	DQO	DQO
Classification	II	II
Indications for use	The AltaTrack Catheter is an angiographic catheter with Fiber Optic RealShape (FORS) technology, intended to deliver radiopaque media or lead a guidewire in endovascular procedures of the peripheral, aortic and aortic side branch vasculature.	The Radifocus Optitorque Angiographic Catheter is indicated for use in cardiac and vascular procedures. It is designed to deliver radiopaque media, guide wires, catheters, and therapeutic agents to selected sites in the vascular system. The different shapes are designed to selectively engage arteries from access sites such as the femoral, radial, and brachial artery.
Application area	Peripheral, aortic and aortic side branch	Selected sites in the vascular system.
Operation principle	Manual	Manual
Specifications	Outer / Inner Diameter: 5.5 Fr / 0.99mm	Outer / Inner Diameter: • 4 Fr / 1.05mm • 5 Fr / 1.22mm • 6 Fr / 1.32mm
	Length: 80 cm	Lengths: 65-120 cm
	Guidewire compatibility: 0.035”	Guidewire compatibility: ≤0.038”
	Maximum Labeled Injection Pressure: Not applicable for manual injection	Maximum Labeled Injection Pressure: • 4 Fr: 750 psi • 5 Fr and 6 Fr: 1000 psi
Packaging	Plastic tray Individual package Unit box Shipping carton Pouch	Paperboard mount Individual package Unit box Shipping carton Pouch
Sterilization method	Ethylene Oxide (EO)	EO

PERFORMANCE TESTING

The performance testing for AltaTrack equipment, AltaTrack Guidewire and AltaTrack Catheter consists of norm-compliance testing, design verification and validation testing. For norm-compliance and design verification, the testing was performed per subject device, while the validation, such as non-clinical validation and usability validation, were performed at system level representing a logical clinical workflow following the intended use.

Performance testing data of the proposed devices demonstrate that the subject devices are substantially equivalent to their predicate devices, and that the design output meets the design input requirements.

Norm-compliance and verification

AltaTrack equipment

Norm-compliance performance testing has been performed on the AltaTrack equipment according to the following FDA recognized consensus standards, and were all passed:

- [Rec. Number: 13-79], IEC 62304 Edition 1.1 2015 Medical device software – Software life cycle processes (Consolidated version)
- [Rec. Number: 5-114], IEC 62366-1:2015 Medical devices – Application of usability engineering to medical devices
- [Rec. Number: 5-117], ISO 15223-Thid Edition 2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
- IEC 60601-1:2005 + A1:2012, Medical electrical equipment edition 3.1 – Part 1: General requirements for basic safety and essential performance[1]
- [Rec. Number: 19-8], IEC 60601-1-2, Edition 4.0, 2014 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances -- Requirements and tests
- [Rec. Number: 12-273], IEC 60825-1:2007 Safety of laser products – Part 1: Equipment classification and requirements
- [Rec. Number: 2-220], ISO 10993-1, Fourth Edition, 2009/A1:2010, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- [Rec. Number: 2-245], ISO 10993-5 Third edition 2009, Biological evaluation of medical devices. Part 5: tests for in vitro cytotoxicity.
- [Rec. Number: 14-408], ANSI AAMI ISO 10993-7:2008(R) 2012, Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
- [Rec. Number: 2-174], ANSI AAMI ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
- [Rec. Number: 14-529], ANSI AAMI ISO 11135:2014, Sterilization of health care products – Ethylene oxide –Requirements for development, validation and routing control of a sterilization process for medical devices
- [Rec. Number: 14-454], ANSI AAMI ISO 11607-1:2006/(R)2010, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barriers systems and packaging systems [Including: Amendment 1 (2014)]
- [Rec. Number: 14-455], ANSI AAMI ISO 11607-2:2006/(R)2010, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]
- [Rec. Number:14-314], AAMI ANSI ST67:2011/(R)2017, Sterilization of healthcare products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled “sterile”

Non-clinical performance testing has been performed to verify the implementation of requirements according to the system requirement specifications, as well as the implementation of identified risk control measures from risk management. The requirements categories include: “Functional Requirements”, “Integration & Interoperability Requirements”, “Configurations, Components and Options”, “User Interface Requirements”, “Service Requirements”, “Manufacturing Requirements” and “Security Requirements”.
Test results demonstrated all executed verification tests have been passed.

[1] Note!: the test report reflects the compliance with [Rec. Number: 19-4], AAMI ANSI 60601-1:2005/R2012 and A1:2012, c1:2009/(r) and A2:2010/(r)2012 Medical electrical equipment edition 3.1 – Part 1: General requirements for basic safety and essential performance.

AltaTrack Guidewire and AltaTrack Catheter

Both AltaTrack Guidewire and AltaTrack Catheter are sterile, single-use devices to be used in peripheral vascular applications. There are commonalities in the list of FDA recognized consensus standards. The following standards for norm-compliance testing are applicable for both AltaTrack Guidewire and AltaTrack Catheter, and all relevant tests for both AltaTrack Guidewire and AltaTrack Catheter have been passed:

- [Rec. Number: 5-114], IEC 62366-1:2015, Medical devices – Application of usability engineering to medical devices
- [Rec. Number: 5-117], ISO 15223-Thid Edition 2016, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
- [Rec. Number: 2-220], ISO 10993-1, Fourth Edition, 2009/A1:2010, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- [Rec. Number: 2-248], ISO 10993-4 Third edition 2017, Biological evaluation of medical devices. Part 4: Selection of tests for interactions with blood
- [Rec. Number: 2-245], ISO 10993-5 Third edition 2009, Biological evaluation of medical devices. Part 5: tests for in vitro cytotoxicity.
- [Rec. Number: 2-250], ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials
- [Rec. Number: 14-408], ANSI AAMI ISO 10993-7:2008(R) 2012, Biological evaluation of medical devices. Part 7: Ethylene oxide sterilization residuals
- [Rec. Number:2-174], ANSI AAMI ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization
- [Rec. Number: 2-255], ISO 10993-11 Third edition 2017, Biological evaluation of medical devices. Part 11: tests for systemic toxicity.
- [Rec. Number: 14-529], ANSI AAMI ISO 11135:2014, Sterilization of health care products – Ethylene oxide –Requirements for development, validation and routing control of a sterilization process for medical devices
- [Rec. Number: 14-454], ANSI AAMI ISO 11607-1:2006/(R)2010, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barriers systems and packaging systems [Including: Amendment 1 (2014)]
- [Rec. Number: 14-455], ANSI AAMI ISO 11607-2:2006/(R)2010, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes [Including: Amendment 1 (2014)]
- [Rec. Number: 14-314], AAMI ANSI ST67:2011/(R)2017, Sterilization of healthcare products - Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled “sterile”

The following standards for norm-compliance testing are applicable for AltaTrack Catheter, and all the applicable tests were passed:

- [Rec. Number: 6-408], ISO 10555-1 Second Edition 2013, Sterile, single-use intravascular catheters -- Part 1: General requirements
- [Rec. Number: 6-11], ISO 594-1:1986, Conical fittings with 6% (luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements
- [Rec. Number: 6-129], ISO 594-2:1998, Conical fittings with 6% (luer) taper for syringes, needles and certain other medical equipment – Part 2: lock fittings

The following FDA guidance was also considered for AltaTrack Guidewire:

- Guidance for Industry and Food and Drug Administration Staff: Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling, October 10, 2019
- Guidance for Industry and Food and Drug Administration Staff: Intravascular Catheters, Wires, and Delivery Systems with Lubricious

Non-clinical performance testing has been performed to verify the requirements for AltaTrack Guidewire and AltaTrack Catheter, respectively. The requirements include dimensional, mechanical, packaging and other safety and/or performance related requirement specifications.
Biocompatibility testing in accordance with ISO 10993

- Cytoxicity
- Sensitization
- Irritation/Intracutaneous reactivity
- Acute Systemic Toxicity
- Material mediated Pyrogenicity
- Hemocompatibility
- Endotoxin

Results demonstrated all verification tests for AltaTrack Guidewire and AltaTrack Catheter have been passed.

Validation testing

Validation testing was performed at system level (AltaTrack system), representing a logical clinical workflow of using AltaTrack equipment, AltaTrack Guidewire and AltaTrack Catheter in combination, to validate that AltaTrack devices conform to their intended use and user needs. The validation was performed with the following testing:

- Animal and phantom testing was executed by a team of vascular surgeons and interventional radiologists with live animal and phantom in a simulated clinical environment. The participants have executed a representative clinical workflow according to a protocol, to validate the intended use, user needs, and effectiveness of the safety related measure. Results demonstrated all study endpoints were met.
- Human factors validation testing:
  Human factors (HF) engineering process was followed in accordance with the following:
  - *IEC 62366-1:2015, Medical devices - Application of usability engineering to medical devices*
  - *FDA Guidance, Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff, Feb 2016*

  The human factors validation test (summative usability evaluation) was performed by teams of intended user groups in a simulated clinical environment in the United States. Each team comprised a physician (interventional radiologist, cardiologist or vascular surgeon), and two OR staff members. Production-equivalent products, with production-equivalent packaging and labels were used in the study. All safety-related-functions (including critical tasks), and all the Frequently Used Functions have been evaluated in the usability study. Results of the summative usability evaluation for critical and non-critical tasks (including all Frequently Used Functions) and interviews with the participants demonstrated that the user interface of the AltaTrack system is safe and effective for the intended users, uses and use environments.
- Customer service validation has been executed to validate the service user needs.

Conclusion on performance testing

All norm-compliance, verification and validation tests have been used to support substantial equivalence of the subject devices and to demonstrate that the AltaTrack devices:

- comply with the aforementioned international and FDA recognized consensus standards and FDA guidance documents; and
- meet the acceptance criteria and are adequate for their intended use.

Based on the information provided above, the AltaTrack devices are considered substantially equivalent to their predicate devices.

No clinical testing was required as substantial equivalence was demonstrated by the attributes of intended use, technological characteristics, and non-clinical testing.

OVERALL CONCLUSION

The proposed devices, AltaTrack equipment, AltaTrack Guidewire and AltaTrack Catheter, are substantially equivalent to the above-mentioned predicate devices, in terms of intended use and technological characteristics.

Substantial equivalence was demonstrated by non-clinical performance tests provided in this 510(k) premarket notification. These tests demonstrate that the proposed devices comply with the user needs specifications and product requirements, as well as the requirements specified in the international and FDA-recognized consensus standards.