510K Summary

as required by 21 CFR 807.92

1. Company Information:
   Contact Person / Official Correspondent: Mr. Tom J Healy
   Regulatory Affairs and Quality Manager
   Name: Brivant Limited (Lake Region Medical)
   Address: Parkmore West Business Park
   Galway Galway, IRELAND
   Establishment Registration Number: 3006010712
   Tel: 091 385 037
   Date prepared: 18 April 2019

2. Product Trade Name: "Hi-Torque Vektor Guidewire Family"
   Common/ Usual Name: "Hi-Torque Vektor"
   Panel: Cardiovascular
   Class II, 21 CFR 870.1330.
   Product Code: DQX.
   Classification Name (per Product Classification): "Catheter guide wire"

3. Predicate Device:
   Manufacturer : Abbott Vascular Inc.
   Device Name : Hi-Torque Pilot 50 Guidewire
   510(k) No : K123067, Class 2, Product Code DQX.
   Classified per 21 CFR 870.1330

   Manufacturer : Asahi Intecc Co. Ltd.
   Device Name : Asahi Fielder XT Guidewire
   510(k) No : K171933, Class 2, Product Code DQX.
   Classified per 21 CFR 870.1330

4. Description of Device:

   The Hi-Torque Vektor Guide Wire is a 0.014" (0.36 mm) diameter steerable guide wire available in several lengths and has a shapeable distal tip. Refer to the product label for product specifications (e.g. wire length, diameter and length of tip radiopacity).

   The Hi-Torque Vektor Guide Wires have a modified proximal end that permits the attachment of the DOC Guide Wire Extension. Refer to the product label for Guide Wire Extension system compatibility. Joining the guide wire extension to the guide wire facilitates the exchange of one interventional device for another, while maintaining guide wire position in the anatomy. After the interventional device exchange has been completed, the extension can be detached and the guide wire can be used in its original capacity.

   Brachial and femoral markers located on the proximal segment of the 0.014" (0.36 mm) Hi-Torque Vektor guide wire aid in gauging guide wire position relative to the guiding catheter

tip when using bare wire technique. These Hi-Torque Vektor guide wires are compatible with guiding catheters that are at least 90 cm (brachial) or 100 cm (femoral) long.

When wet, a hydrophilic coating increases the lubricity of the Hi-Torque Vektor guide wire surface. This coating contains highly purified hyaluronic acid (HA).

Principles of Operation: The Hi-Torque Vektor guidewire is operated manually by a manual process.

5. Indications for Use

Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.

6. Comparison of Technological Characteristics

The technological characteristics are substantially equivalent to the predicate device. These performance properties include:

- Similar length range provided
- Same diameter (0.014")
- All devices are constructed with a stainless steel core
- The proposed 4 models have equivalent tip stiffness characteristics to the predicate devices.
- All devices have a hydrophilic coating at the distal tip
- All devices have a PTFE coating on the guidewire shaft
- All devices are sterilized using ETO gas

7. Performance Testing (non-clinical)

In vitro bench tests were carried out to demonstrate equivalence with reference to the FDAs guidance document "Coronary and Cerebrovascular Guidewire Guidance, Jan 1995". The following bench tests were performed:

- Tensile Strength
- Torque Strength
- Dimensional measurement
- Torque Response
- Catheter Compatibility
- Coating Adherence/Coating Integrity
- Coating Lubricity and Durability
- Particulate Testing
- Tip Flexibility/Stiffness
- Radiopacity

- Corrosion Res
- Flex Resistance Test
- Guidewire Pull test

The results from these performance evaluations demonstrated that the Hi-Torque Vektor Guidewire range met the acceptance criteria defined in the product specification and performed comparably to the predicate device(s).

Biological compatibility of the device has been established through biocompatibility testing carried out in compliance with ISO 10993-1.

See Table 1.0 for comparison with above mentioned predicate devices.

Table 1.0: Predicate Comparison Table

	Equivalence Category	Hi-Torque Vektor (Proposed Device)	Hi-Torque Pilot 50 (Primary Predicate)	Fielder XT (Secondary Predicate)
Manufacturer:	N/A	Lake Region Medical	Abbott Vascular	Asahi Intecc
EU Classification	Clinical	III	III	III (unknown but expected Class III)
US Classification	Clinical	II	II	II
Classification Name	Clinical	Catheter Guide Wire	Catheter Guide Wire	Catheter Guide Wire
FDA Classification Product Code	Clinical	DQX	DQX	DQX
Indications for Use	Clinical	Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature.	Intended to facilitate the delivery of catheter-based interventional devices during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA). This guide wire may be used with compatible stent devices during therapeutic procedures. The guide wire may be used to reach and cross a target lesion, provide a pathway within the vessel structure, facilitate the substitution of one diagnostic or interventional device for another, and to distinguish the vasculature. This guide wire may also be used to cross or assist in crossing *de novo* chronic total coronary occlusions (CTO)	ASAHI PTCA Guide Wires are intended to facilitate the placement of balloon dilatation catheters during percutaneous transluminal coronary angioplasty (PTCA) and percutaneous transluminal angioplasty (PTA), including use in crossing or assisting in crossing de novo coronary chronic total occlusions (CTO).
Contraindications	Clinical	Not intended for use in the cerebral vasculature or with atherectomy devices	Not intended for use in the cerebral vasculature or with atherectomy devices	The ASAHI PTCA Guide Wires are not to be used in the neurovasculature.

Anatomical sites	Clinical	Coronary & Peripheral Vasculature	Coronary & Peripheral Vasculature	Coronary & Peripheral Vasculature
Operating Principle	Clinical	Device is hand held and operated by manual method. User will hold, rotate, push and pull the wire to steer it through the vasculature	Device is hand held and operated by manual method. User will hold, rotate, push and pull the wire to steer it through the vasculature	Device is hand held and operated by manual method. User will hold, rotate, push and pull the wire to steer it through the vasculature
Single patient device	Clinical	Yes	Yes	Yes
Single use or reusable	Clinical	Single Use	Single Use	Single Use
Medical user qualification	Clinical	Interventional Cardiologist, Interventional Radiologist	Interventional Cardiologist, Interventional Radiologist	Interventional Cardiologist, Interventional Radiologist
Deployment Method	Clinical	Guidewire insertion shall be via femoral / radial access and introduced to the body via an introducer/ sheath / guide catheter/ etc. The guidewire is then directed to the target location by manual manipulation	Guidewire insertion shall be via femoral / radial access and introduced to the body via an introducer/ sheath / guide catheter/ etc. The guidewire is then directed to the target location by manual manipulation	Guidewire insertion shall be via femoral / radial access and introduced to the body via an introducer/ sheath / guide catheter/ etc. The guidewire is then directed to the target location by manual manipulation
Patient Population	Clinical	Age: Adult over the age of 16 Weight: No average	Age: Adult over the age of 16 Weight: No average	Age: Adult over the age of 16 Weight: No average
Clinical Condition	Clinical	Cardiac and Peripheral Vascular Disease Other co-morbidity conditions may apply such as diabetes, hypertension, hyperlipidemia, atherosclerosis, CHF, and Previous MI.	Cardiac and Peripheral Vascular Disease Other co-morbidity conditions may apply such as diabetes, hypertension, hyperlipidemia, atherosclerosis, CHF, and Previous MI.	Cardiac and Peripheral Vascular Disease Other co-morbidity conditions may apply such as diabetes, hypertension, hyperlipidemia, atherosclerosis, CHF, and Previous MI.
Materials and Biocompatibility	Biological	Stainless Steel Core	Stainless Steel Core	Stainless Steel Core
		Platinum Tungsten Alloy	Platinum Tungsten Coil	Platinum Tungsten Coil
		Solder	Solder	Solder
		Polyurethane	Polyurethane	Polyurethane
		PTFE Coating	PTFE Coating	PTFE Coating
		Hydrophilic Coating	Hydrophilic Coating –	Hydrophilic Coating –

Sterilization Status	Technical	Supplied Sterile	Supplied Sterile	Supplied Sterile
Packaging	Technical	Tyvek, heat sealed to a film of PET/PE Sterile Packaging	Tyvek, heat sealed to a film of PET/PE Sterile Packaging (unknown but assumed)	Tyvek, heat sealed to a film of PET/PE Sterile Packaging (unknown but assumed)
Overall Design & Construction	Technical	PTFE coated stainless steel core wire with a tapered distal grind section to impart flexibility. Radiopaque platinum/tungsten coil soldered at the distal tip. Coil and core distal section are encapsulated in a tungsten doped polyurethane jacket. Hydrophilic coating applied to the polyurethane jacket	PTFE coated stainless steel core wire with a tapered distal grind section to impart flexibility. Radiopaque platinum/tungsten coil soldered at the distal tip. Coil and core distal section are encapsulated in a polyurethane jacket. Hydrophilic coating applied to the polyurethane jacket	PTFE coated stainless steel core wire with a tapered distal grind section to impart flexibility. Radiopaque platinum/tungsten coil soldered at the distal tip. Coil and core distal section are encapsulated in a polyurethane jacket. Hydrophilic coating applied to the polyurethane jacket
Core Design	Technical	Core to Tip	Core to Tip	Core to Tip
Guidewire Length	Technical	195cm, 300cm	190cm, 300cm	190cm, 300cm
Guidewire Nominal Diameter	Technical	0.014”	0.014”	0.014”
PTFE Coating Diameter	Technical	0.014” maximum	0.014” maximum	0.014” maximum
Polymer Jacket Length	Technical	22cm	29cm	16cm
Polymer Jacket Diameter	Technical	0.014” maximum	0.014” maximum	0.014” maximum
Torque Response	Technical	Equivalent torque response to Pilot 50 and Fielder XT	Equivalent torque response to Hi-Torque Vektor	Equivalent torque response to Hi-Torque Vektor
Hydrophilic Coating Lubricity	Technical	The Hi-Torque Vektor demonstrated higher lubricity pinch forces than the Hi-Torque Pilot 50 when tested using this test method. The Hi-Torque Vektor demonstrated lower lubricity pinch forces than the Fielder XT when tested using this test method.	The Hi-Torque Pilot 50 demonstrated lower lubricity pinch forces than the Hi-Torque Vektor when tested using this test method.	The Fielder XT demonstrated higher lubricity pinch forces than the Hi-Torque Vektor when tested using this test method.
Hydrophilic Coating Durability	Technical	The Hi-Torque Vektor demonstrated superior hydrophilic coating durability	The Hi-Torque Pilot 50 demonstrated inferior hydrophilic coating durability to the Hi-	The Fielder XT demonstrated inferior hydrophilic coating durability to the Hi-

		to the Hi-Torque Pilot 50 when tested using this test method. The Hi-Torque Vektor demonstrated superior hydrophilic coating durability to the Fielder XT when tested using this test method.	Torque Vektor when tested using this test method.	Torque Vektor when tested using this test method.
Device / Catheter Compatibility	Technical	Equivalent compatibility characteristics to Hi-Torque Pilot 50 and Fielder XT	Equivalent compatibility characteristics to Hi-Torque Vektor	Equivalent compatibility characteristics to Hi-Torque Vektor
Coating Adherence / Integrity	Technical	Equivalent coating adherence / integrity characteristics to Hi-Torque Pilot 50 and Fielder XT when tested using this test method	Equivalent coating adherence / integrity characteristics to Hi-Torque Vektor	Equivalent coating adherence / integrity characteristics to Hi-Torque Vektor
Kink Resistance	Technical	Equivalent (body) / Superior (tip) kink resistance to Hi-Torque Pilot 50 Equivalent kink resistance to Fielder XT (body & tip)	Equivalent (body) / Inferior (tip) kink resistance to Hi-Torque Vektor	Equivalent (body & tip) kink resistance to Hi-Torque Vektor
Particulate Residue	Technical	Equivalent particulate residue to Hi-Torque Pilot 50 and Fielder XT - all parts meet the specification	Equivalent particulate residue to Hi-Torque Vektor - all parts meet the specification	Equivalent particulate residue to Hi-Torque Vektor - all parts meet the specification
Radiopacity	Technical	Radiopaque platinum/tungsten coil	Radiopaque platinum/tungsten coil	Radiopaque platinum/tungsten coil
Corrosion Resistance	Technical	Equivalent corrosion resistance properties to Hi-Torque Pilot 50 and Fielder XT	Equivalent corrosion resistance properties to Hi-Torque Vektor	Equivalent corrosion resistance properties to Hi-Torque Vektor

ISO Flex Resistance Test (Bending Durability)	Technical	Equivalent bending durability properties to Hi-Torque Pilot 50 and Fielder XT	Equivalent bending durability properties to Hi-Torque Vektor	Equivalent bending durability properties to Hi-Torque Vektor
Extension Capability	Technical	The Hi-Torque Vektor has extension capability and is compatible with the Abbott DOC extension system (identical to Hi-Torque Pilot 50). Hi-Torque Vektor has demonstrated improved performance compared to Hi-Torque Pilot 50	The Hi-Torque Pilot has extension capability and is compatible with the Abbott DOC extension system (identical to Hi-Torque Vektor). Hi-Torque Vektor has demonstrated improved performance compared to Hi-Torque Pilot 50	The Fielder XT has extension capability (with Asahi extension system)
Tip Shapeability	Technical	Shapeable Tip	Shapeable Tip	Shapeable Tip
Pre-Formed 'J' Tips Offered	Technical	The Hi-Torque Vektor is offered with a straight tip and an additional pre-formed J tip	The Hi-Torque Pilot 50 is offered with a straight tip and an additional pre-formed J tip	The Fielder XT is offered in straight tip only
Shaft Depth Markings	Technical	The Hi-Torque Vektor has shaft depth markings / indicators	The Hi-Torque Pilot has shaft depth markings / indicators	The Fielder XT does not have shaft markings / indicators
Proximal Wire Identifier	Technical	The Hi-Torque Vektor has a proximal wire identifier	The Hi-Torque Pilot 50 does not have a proximal wire identifier	The Fielder XT does not have a proximal wire identifier

8. Conclusion

   Based on performance testing, technological characteristics and the indications for use for the device, the Hi-Torque Vektor Guidewire has been demonstrated to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.