

February 10, 2022

CathRx Ltd % Amy Oakes Quality & Regulatory Consultant Acorn N Oakes LLC 333 N. Dobson Rd. Suite 5 Chandler, Arizona 85224

Re: K211327

Trade/Device Name: Khelix Diagnostic Electrophysiology Catheters

Regulation Number: 21 CFR 870.1220

Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe

Regulatory Class: Class II

Product Code: DRF Dated: April 6, 2021 Received: May 3, 2021

Dear Amy Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/efdocs/efpmn/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 <u>Federal Register</u>.

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-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">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,

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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

510(k) Number (if known)

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023 See PRA Statement below.

K211327
Device Name
Khelix Diagnostic Electrophysiology Catheters
Indications for Use (Describe) The Khelix Diagnostic Electrophysiology Catheters are indicated for the electrical recording or stimulation of endocardial structures. The loop versions of the catheters are intended for obtaining and recording electrograms from the atrial region of the heart.
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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SECTION 5: 510(K) SUMMARY

Submitter's Name and Address:

CathRx Ltd Unit 8, 2-8 South St Rydalmere NSW 2116, Australia

Owner Name and Information

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Date Prepared:

March 24, 2021

Device Information:

Trade/Proprietary Name: Khelix Diagnostic Electrophysiology Catheters

Common Name: Diagnostic Electrophysiology Catheters

Classification Name: Electrode Recording Catheter or electrode recording probe

Classification Number: 21 CFR 870.1220

Product Code: DRF

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K113213	Lasso NAV 2515 Variable	Biosense Webster

Table 5.1: Predicate Device



Manufacturer:

CathRx Ltd Unit 8, 2-8 South St Rydalmere NSW 2116, Australia

Manufacturing Facilities:

Manufacturing
CathRx Ltd
Unit 8, 2-8 South St
Rydalmere
NSW 2116, Australia

Sterilization
5 and 7 Widemere Rd,
Wetherill Park
NSW 2164, Australia

Device Description:

Khelix Diagnostic Electrophysiology Catheters are a range of electrophysiology diagnostic cardiac catheters designed to facilitate electrophysiological mapping of the heart. The devices are intended for the electrical recording and/or stimulation of endocardial structures.

The Khelix Diagnostic Electrophysiology Catheter range is used by cardiologists in electrophysiology (EP) studies to determine the cause of an abnormal heart rhythm, to locate the site of origin of an abnormal heart rhythm, to decide the best treatment for an abnormal heart rhythm, and/or to check the effectiveness of ablation therapy. An EP study is sometimes conducted before placement of an implantable cardioverter/defibrillator (ICD) to determine the best type of device, and to monitor treatment effectiveness.

The device consists of a catheter handle and catheter shaft containing an array of platinum-iridium electrodes for stimulation and recording. The subject device comes in a variety of models based on the distal catheter configuration including Steerable and Loop models. The device interfaces with standard electrophysiological recording equipment, such as ECG monitoring equipment, impedance based navigational equipment and cardiac stimulation equipment, via the Khelix Diagnostic Extension Cable (supplied separately). The device is available in different device models with several variants according to electrode configurations, curve types and loop diameters, as applicable. A full list of model variants is detailed at the end of this summary.

The subject catheters use 4 to 20 electrodes with variable spacing to provide for variation in physician preference.

The catheter is intended to be used with the Khelix Diagnostic Extension Cable. The extension cable connects distally to the catheter (sterile field) and proximally to standard electrophysiology (EP) laboratory equipment such as heart signal monitors/records and stimulators (non-sterile field) via shielded tip pins.



The Khelix Diagnostic Electrophysiology Catheter range is supplied sterile. The devices are sterilized using an ethylene oxide (EtO) sterilization process.

Indications for Use:

The Khelix Diagnostic Electrophysiology Catheters are indicated for the electrical recording or stimulation of endocardial structures. The loop versions of the catheters are intended for obtaining and recording electrograms from the atrial region of the heart.

Technological Characteristics:

A high-level comparison of the proposed and predicate devices is in Table 5.2 below:

Characteristic	Predicate Device	Subject Device	Comparison
Product Code	DRF	DRF	Identical
Operating Principles / Mechanism of	Electrical	Electrical	Identical
Action	Stimulation &	Stimulation &	
	Recording	Recording	
Materials	PEBAX insulation	PEBAX insulation	Identical
	with platinum	with platinum	
	electrodes	electrodes	
Key technological characteristics	Τ	T	Equivalent
Fr Size	7 Fr	6Fr, 7Fr	Equivalent
Working Length	115 cm	115 cm	Identical
Deflection Plane	In Plane	In Plane	Identical
Deflection Type	Unidirectional	Unidirectional	Identical
# of Electrodes	10-20	4-20	Equivalent
Electrode Spacing	2-6-2mm (20 pole)	2-5-2mm	Equivalent
	8-8-8mm (10 pole)	2-2-2mm	
	In Lasso Nav fixed	5-5-5mm	
	loop catheters:	2-8-2mm	
	5-5-5mm (15mm)	2-10-2mm	
	6-6-6mm (20mm)	2-12-2mm	
	8-8-8mm (25mm)		
Tip Electrode	Passive	Passive	Identical
Loop Diameter	25-15 mm	25-15 mm	Identical
Curve Shape	D Curve (6.4 cm)	D-curve (40.7mm)	Equivalent
		Other curve sizes	
		available:	
		F-curve (48.3mm)	
		G- curve	
		(56.6mm)	
		J-curve (64.9mm)	
		P-curve (80.8mm)	
		Q-curve (96.7mm)	
		R-curve	
		(113.3mm)	
		(113.311111)	



Characteristic	Predicate Device	Subject Device	Comparison
Accessory Devices	Extension Cable	Extension Cable	Identical
Environment of use	Cath Lab	Cath Lab	Identical
Sterility & Reusability	Single Use	Single Use	Identical
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Identical

Table 5.2: Comparison Table

The purpose, design, materials, function, and intended use of the Khelix Diagnostic Electrophysiology Catheters are substantially equivalent to the predicate devices.

Function and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Khelix Diagnostic Electrophysiology Catheters.

Testing includes the following:

Test		Test Methodology	Result
Sterili	zation Validation	ISO 11135	Pass
	SAL = 10 ⁻⁶	ISO 11135	Pass
	EO Residuals	ISO 10993-7	Pass
Bioco	mpatibility	ISO 10993	Pass
		ASTM 756	
Packa	ging Validation	ASTM 4332	Pass
		ASTM 4169	
	Shelf Life	ASTM F1980	Pass
		ISO 11607	
	Sterile Barrier Integrity	ASTM F1886/F1886M-16	Pass
		ASTM F2096-11 (2019)	
		ASTM F88/F88M-15	
Electr	ical Safety Testing	IEC 60601-1	Pass
		IEC 60601-1-2	
		IEC 60601-2-27	
Funct	ional Performance Testing	ISO 10555-1	Pass
	Attribute Inspection	Visual inspection to	Pass
		workmanship standards	
	Mechanical Characterization	N/A	Pass
	Functional Performance	N/A	Pass
	Simulated Use	N/A	Pass
	Joint Strength (Integrity)	ISO 10555-1	Pass

Conclusion:

CathRx concludes that the Khelix Diagnostic Electrophysiology Catheters are substantially equivalent to the predicate device described herein.



Khelix Diagnostic Electrophysiology Catheters

Steerable Models

Product Reference	Allocated Item	Curve Length	Deflection	Deflection Type	# of	Tip Electrode	Spacing (mm)
Number	Number	(cm)	Plane		Electrodes		
SS1-D0U-04P6222							2-2-2
SS1-D0U-04P6252							
SS1-D0U-04P6555					4		5-5-5
SS1-D0U-04P6282							2-8-2
SS1-D0U-04P62102							2-10-2
SS1-D0U-06P6222]	2-2-2
SS1-D0U-06P6252					6	Descius	2-5-2
SS1-D0U-06P6555							5-5-5
SS1-D0U-06P6282			6.4 In Plane Unidirectional –				2-8-2
SS1-D0U-06P62102		C 4		l la idina ational			2-10-2
SS1-D0U-08P6222		0.4		8	Passive	2-2-2	
SS1-D0U-08P6252						2-5-2	
SS1-D0U-08P6555						5-5-5	
SS1-D0U-08P6282						2-8-2	
SS1-D0U-08P62102							2-10-2
SS1-D0U-10P6222]	2-2-2
SS1-D0U-10P6252							2-5-2
SS1-D0U-10P6555					10		5-5-5
SS1-D0U-10P6282							2-8-2
SS1-D0U-10P62102							2-10-2



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS1-F0U-04P6222							2-2-2
SS1-F0U-04P6252							2-5-2
SS1-F0U-04P6555					4		5-5-5
SS1-F0U-04P6282							2-8-2
SS1-F0U-04P62102							2-10-2
SS1-F0U-06P6222							2-2-2
SS1-F0U-06P6252							2-5-2
SS1-F0U-06P6555				6		5-5-5	
SS1-F0U-06P6282							2-8-2
SS1-F0U-06P62102		7.6	In Plane	Unidirectional		Dossivo	2-10-2
SS1-F0U-08P6222		7.6	in Plane	Unidirectional		Passive	2-2-2
SS1-F0U-08P6252							2-5-2
SS1-F0U-08P6555					8		5-5-5
SS1-F0U-08P6282							2-8-2
SS1-F0U-08P62102							2-10-2
SS1-F0U-10P6222							2-2-2
SS1-F0U-10P6252							2-5-2
SS1-F0U-10P6555					10		5-5-5
SS1-F0U-10P6282							2-8-2
SS1-F0U-10P62102							2-10-2



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS1-G0U-04P6222							2-2-2
SS1-G0U-04P6252							2-5-2
SS1-G0U-04P6555					4		5-5-5
SS1-G0U-04P6282							2-8-2
SS1-G0U-04P62102							2-10-2
SS1-G0U-06P6222							2-2-2
SS1-G0U-06P6252							2-5-2
SS1-G0U-06P6555			6		5-5-5		
SS1-G0U-06P6282						Passivo	2-8-2
SS1-G0U-06P62102		0.0	In Diana	- Plana - Linisina atiana l			2-10-2
SS1-G0U-08P6222		8.9	In Plane	Unidirectional		Passive	2-2-2
SS1-G0U-08P6252							2-5-2
SS1-G0U-08P6555		1			8		5-5-5
SS1-G0U-08P6282							2-8-2
SS1-G0U-08P62102		1					2-10-2
SS1-G0U-10P6222							2-2-2
SS1-G0U-10P6252		1					2-5-2
SS1-G0U-10P6555					10		5-5-5
SS1-G0U-10P6282							2-8-2
SS1-G0U-10P62102							2-10-2



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS1-J0U-04P6222							2-2-2
SS1-J0U-04P6252							2-5-2
SS1-J0U-04P6555					4		5-5-5
SS1-J0U-04P6282							2-8-2
SS1-J0U-04P62102							2-10-2
SS1-J0U-06P6222							2-2-2
SS1-J0U-06P6252							2-5-2
SS1-J0U-06P6555					6		5-5-5
SS1-J0U-06P6282							2-8-2
SS1-J0U-06P62102		10.3	In Diana	l lucialina attia mal		Danius	2-10-2
SS1-J0U-08P6222		10.2	In Plane	Unidirectional		Passive	2-2-2
SS1-J0U-08P6252							2-5-2
SS1-J0U-08P6555					8		5-5-5
SS1-J0U-08P6282							2-8-2
SS1-J0U-08P62102							2-10-2
SS1-J0U-10P6222							2-2-2
SS1-J0U-10P6252							2-5-2
SS1-J0U-10P6555					10		5-5-5
SS1-J0U-10P6282							2-8-2
SS1-J0U-10P62102							2-10-2



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)	
SS1-P0U-04P6222							2-2-2	
SS1-P0U-04P6252							2-5-2	
SS1-P0U-04P6555					4		5-5-5	
SS1-P0U-04P6282					4		2-8-2	
SS1-P0U-04P62102							2-10-2	
SS1-P0U-04P6101010							10-10-10	
SS1-P0U-06P6222							2-2-2	
SS1-P0U-06P6252							2-5-2	
SS1-P0U-06P6555			.7 In Plane Unid		6		5-5-5	
SS1-P0U-06P6282						U		2-8-2
SS1-P0U-06P62102					8	Passive	2-10-2	
SS1-P0U-06P6101010		12.7		Unidirectional			10-10-10	
SS1-P0U-08P6222		12.7	III Flatie	Unidirectional			2-2-2	
SS1-P0U-08P6252							2-5-2	
SS1-P0U-08P6555							5-5-5	
SS1-P0U-08P6282					0		2-8-2	
SS1-P0U-08P62102							2-10-2	
SS1-P0U-08P6101010							10-10-10	
SS1-P0U-10P6222							2-2-2	
SS1-P0U-10P6252							2-5-2	
SS1-P0U-10P6555					10		5-5-5	
SS1-P0U-10P6282					10		2-8-2	
SS1-P0U-10P62102							2-10-2	
SS1-P0U-10P6101010					I		10-10-10	



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS1-Q0U-04P6222							2-2-2
SS1-Q0U-04P6252							2-5-2
SS1-Q0U-04P6555					4		5-5-5
SS1-Q0U-04P6282					4		2-8-2
SS1-Q0U-04P62102							2-10-2
SS1-Q0U-04P6101010							10-10-10
SS1-Q0U-06P6222							2-2-2
SS1-Q0U-06P6252						Passive	2-5-2
SS1-Q0U-06P6555							5-5-5
SS1-Q0U-06P6282				ne Unidirectional			2-8-2
SS1-Q0U-06P62102							2-10-2
SS1-Q0U-06P6101010		15.2	In Plane				10-10-10
SS1-Q0U-08P6222		15.2	III Flatie	Official			2-2-2
SS1-Q0U-08P6252							2-5-2
SS1-Q0U-08P6555							5-5-5
SS1-Q0U-08P6282					0		2-8-2
SS1-Q0U-08P62102							2-10-2
SS1-Q0U-08P6101010							10-10-10
SS1-Q0U-10P6222							2-2-2
SS1-Q0U-10P6252							2-5-2
SS1-Q0U-10P6555					10		5-5-5
SS1-Q0U-10P6282					10		2-8-2
SS1-Q0U-10P62102							2-10-2
SS1-Q0U-10P6101010					1		10-10-10



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)	
SS1-R0U-04P6222							2-2-2	
SS1-R0U-04P6252							2-5-2	
SS1-R0U-04P6555					4		5-5-5	
SS1-R0U-04P6282					4		2-8-2	
SS1-R0U-04P62102							2-10-2	
SS1-R0U-04P6101010							10-10-10	
SS1-R0U-06P6222							2-2-2	
SS1-R0U-06P6252							2-5-2	
SS1-R0U-06P6555					6		5-5-5	
SS1-R0U-06P6282			La Blanca			O		2-8-2
SS1-R0U-06P62102					8	- Passive	2-10-2	
SS1-R0U-06P6101010		17.8		Unidirectional			10-10-10	
SS1-R0U-08P6222		17.8	In Plane	Unidirectional			2-2-2	
SS1-R0U-08P6252							2-5-2	
SS1-R0U-08P6555							5-5-5	
SS1-R0U-08P6282							2-8-2	
SS1-R0U-08P62102							2-10-2	
SS1-R0U-08P6101010							10-10-10	
SS1-R0U-10P6222							2-2-2	
SS1-R0U-10P6252							2-5-2	
SS1-R0U-10P6555					10		5-5-5	
SS1-R0U-10P6282					10		2-8-2	
SS1-R0U-10P62102							2-10-2	
SS1-R0U-10P6101010		1					10-10-10	



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS1-Y0U-04P6222							2-2-2
SS1-Y0U-04P6252							2-5-2
SS1-Y0U-04P6555					4		5-5-5
SS1-Y0U-04P6282					4		2-8-2
SS1-Y0U-04P62102							2-10-2
SS1-Y0U-04P6101010							10-10-10
SS1-Y0U-06P6222							2-2-2
SS1-Y0U-06P6252						Passive	2-5-2
SS1-Y0U-06P6555					6		5-5-5
SS1-Y0U-06P6282					Ü		2-8-2
SS1-Y0U-06P62102		6.4 HIS	In Plane	Unidirectional			2-10-2
SS1-Y0U-06P6101010							10-10-10
SS1-Y0U-08P6222		0.41113		Official			2-2-2
SS1-Y0U-08P6252							2-5-2
SS1-Y0U-08P6555					8		5-5-5
SS1-Y0U-08P6282					0		2-8-2
SS1-Y0U-08P62102							2-10-2
SS1-Y0U-08P6101010							10-10-10
SS1-Y0U-10P6222							2-2-2
SS1-Y0U-10P6252							2-5-2
SS1-Y0U-10P6555					10		5-5-5
SS1-Y0U-10P6282					10		2-8-2
SS1-Y0U-10P62102							2-10-2
SS1-Y0U-10P6101010							10-10-10



Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Plane	Deflection Type	# of Electrodes	Tip Electrode	Spacing (mm)
SS2-P0U-20P6242							2-4-2
SS2-P0U-20P6282	CCD0104						2-8-2
SS2-P0U-20P62102		1				Passive	2-10-2
SS2-P0U-20P62122	CCD0042]					2-12-2
SS2-P0U-20P62132		1					2-13-2
SS2-P0U-20P620282		1					20-2-8-2
SS2-Q0U-20P6242		1					2-4-2
SS2-Q0U-20P6282		1					2-8-2
SS2-Q0U-20P62102		1					2-10-2
SS2-Q0U-20P62122	CCD0089]				Passive	2-12-2
SS2-Q0U-20P62132		1					2-13-2
SS2-Q0U-20P620282		1					20-2-8-2
SS2-R0U-20P6242		1					2-4-2
SS2-R0U-20P6282		1					2-8-2
SS2-R0U-20P62102		1				Passive	2-10-2
SS2-R0U-20P62122	CCD0090	1					2-12-2
SS2-R0U-20P62132							2-13-2
SS2-R0U-20P620282		1					20-2-8-2

Product Reference	Allocated Item	Curve Length	Deflection	Deflection Type	# of	Tip Electrode	Spacing (mm)
Number	Number	(cm)	Plane		Electrodes		
SS2-Y0U-20P6242							2-4-2
SS2-Y0U-20P6282							2-8-2
SS2-Y0U-20P62102						Passive	2-10-2
SS2-Y0U-20P62122						Passive	2-12-2
SS2-Y0U-20P62132							2-13-2
SS2-Y0U-20P620282							20-2-8-2

Loop Fixed Models



Product Reference	Allocated Item	Curve	Loop Type	Loop Size (mm)	# of	Tip Electrode	Spacing (mm)
Number	Number				Electrodes		
SCF-S15-10P7555				15			5-5-5
SCF-S20-10P7666		Straight	Fixed	20	10	Passive	6-6-6
SCF-S25-10P7888				25	10		8-8-8
SCF-S30-10P7999				30			9-9-9

Fixed Loop Steerable Models

Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Type	Loop Type	Loop Size (mm)	# of Electrodes	Tip Electrode	Spacing (mm)
SC1-B15U-10P7555	CCD0051				15			5-5-5
SC1-B20U-10P7666	CCD0052	5.1			20			6-6-6
SC1-B25U-10P7888	CCD0053		l lucialina ati a u a l	Fired	25	10	Danairea	8-8-8
SC1-D15U-10P7555			- Unidirectional	Fixed	15	10	Passive	5-5-5
SC1-D20U-10P7666		6.4		,	20			6-6-6
SC1-D25U-10P7888					25			8-8-8

Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Type	Loop Type	Loop Size (mm)	# of Electrodes	Tip Electrode	Spacing (mm)
SC2-B15U-14P7333					15			3-3-3
SC2-B20U-14P7444					20	14	- Passive	4-4-4
SC2-B30U-14P7777		5.1			30			7-7-7
SC2-B15U-20P7232			- Unidirectional		15	20		2-3-2
SC2-B20U-20P7242					20			2-4-2
SC2-B25U-20P7262				Fined	25			2-6-2
SC2-B30U-20P7272					30			2-7-2
SC2-D15U-14P7333				Fixed	15			3-3-3
SC2-D20U-14P7444					20			4-4-4
SC2-D30U-14P7777					30			7-7-7
SC2-D15U-20P7232		6.4			15			2-3-2
SC2-D20U-20P7242					20	20		2-4-2
SC2-D25U-20P7262					25			2-6-2
SC2-D30U-20P7272					30			2-7-2



Variable Loop Steerable Models

Product Reference Number	Allocated Item Number	Curve Length (cm)	Deflection Type	Loop Type	Loop Size (mm)	# of Electrodes	Tip Electrode	Spacing (mm)
SC2-B2515U-10P7888	CCD0069	E 1	Unidirectional	Variable	25-15	10	Passive	8-8-8
SC2-B2515U-20P7262	CCD0040	5.1	Unidirectional	Variable		20	rassive	2-6-2