Section 5: Traditional 510(k) Summary

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Device Trade Name: Makoto Intravascular Imaging System™, TVC-MC10 / TVC-MC10i
Dualpro IVUS + NIRS Imaging Catheter™, TVC-C195-42

Common or Usual Name: Ultrasonic Pulsed Echo Imaging System
Diagnostic Intravascular Catheter

Classification: 21 CFR 892.1560, 21 CFR 870.1200
Class: II
Product Code: IYO, OGZ

Predicate Device(s): TVC Imaging System™, TVC-MC10/TVC-MC10i
TVC Catheter™, TVC-C195-42 (K163345)

Device Description: The Makoto Intravascular Imaging System™ is an intravascular imaging device with the ability to simultaneously assess vessel composition and structure using near-infrared spectroscopy (NIRS) and intravascular ultrasound (IVUS). This dual-modality instrument performs near-infrared spectroscopic analysis of the vessel to detect lipid core-containing plaques of interest (LCP) displayed in a map called a Chemogram, and simultaneously generates high resolution IVUS images that display structural details of the vessel and plaque in transverse and longitudinal views.

Indication for Use:

1. The Makoto Intravascular Imaging System™ is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography.
   a. The System is intended for the detection of lipid-core-containing plaques of interest.
   b. The System is intended for the assessment of coronary artery lipid core burden.
   c. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.
2. The System is intended for ultrasound examination of coronary intravascular pathology.
   a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Technological Characteristics: The Makoto Intravascular Imaging System™ is composed of three main components: the Catheter, the Controller (Pullback and Rotation Device (PBR)), and the Console. These three interconnected components work together to produce dual images of NIRS and IVUS in a single scan of the vessel.

The proposed device has the same technological characteristics, design and configuration as the currently marketed predicate device (K163345). The tables below compare the general, catheter, controller, and console characteristics of the proposed and predicate devices.

General Characteristics:			
Characteristic	**Predicate TVC-C195-42 and TVC-MC10, MC10i (K163345)**	**Proposed Device * TVC-C195-42 and TVC-MC10, MC10i**	**Comparison with Predicate Device**
Product Function	Near Infrared and Ultrasound Imaging System	Near Infrared and Ultrasound Imaging System	Same
Intended Use	The TVC Imaging System™ is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography. The System is intended for the detection of lipid-core-containing plaques of interest. The System is intended for the assessment of coronary artery lipid core burden. The System is intended for ultrasound examination of coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	The Makoto Intravascular Imaging System™ is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography. The System is intended for the detection of lipid-core-containing plaques of interest. The System is intended for the assessment of coronary artery lipid core burden. The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events. The System is intended for ultrasound examination of coronary intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	Substantially Equivalent
Where Used	Coronary	Coronary	Same
System Components	NIR/IVUS Catheter Portable or Fixed Console (Laser, SBC, power supply) and Controller	NIR/IVUS Catheter Portable or Fixed Console (Laser, SBC, power supply) and Controller	Same

Classification	Catheter – Product Code OGZ 21 CFR 870.1200 System Product Code IYO 21 CFR 892.1560	Catheter – Product Code OGZ 21 CFR 870.1200 System Product Code IYO 21 CFR 892.1560	Same
Clinical data in 510(k)	No	Yes	Substantially Equivalent

* The TVC Imaging System and the TVC Catheter (K163345) were re-branded in September, 2017 to the Makoto Intravascular Imaging System and the Dualpro IVUS + NIRS Imaging Catheter. The original model numbers, TVC-MC10/TVC-MC10i and TVC-C195-42, remained the same under the new brand.

Catheter Characteristics:

Characteristic	Predicate TVC-C195-42 and TVC-MC10, MC10i (K163345)	Proposed Device TVC-C195-42 and TVC-MC10, MC10i	Comparison with Predicate Device
Usable Length	160 cm	160 cm	Same
Sheath Distal Tip Profile	2.4 F	2.4 F	Same
Guidewire rail length	1.2 cm	1.2 cm	Same
Imaging window profile	3.2 F	3.2 F	Same
Imaging core pullback	15 cm	15 cm	Same
Number of RO Marker Bands	1 RO marker (0.5cm from distal tip)	1 RO marker (0.5cm from distal tip)	Same
Maximum guidewire OD	0.014 in.	0.014 in.	Same
Minimum guide catheter I.D.	6 F	6 F	Same
Method of Sterilization	EtO	EtO	Same
Packaging	Card/pouch	Card/pouch	Same
Materials supplied in sterile packaging	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Intravascular NIR/IVUS catheter Priming accessory Controller sterile barrier	Same
Shelf Life	6 months	18 months	Substantially Equivalent
Transducer Center Frequency	50MHz	50MHz	Same

Controller and Console Characteristics:

Characteristic	Predicate TVC-C195-42 and TVC-MC10, MC10i (K163345)	Proposed Device TVC-C195-42 and TVC-MC10, MC10i	Comparison with Predicate Device
Imaging Mode	Near Infrared light, Ultrasound	Near Infrared light, Ultrasound	Same
Output	NIR light RF Ultrasound	NIR light RF Ultrasound	Same

Hardware Components	CPU with 16GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	CPU with 16GB RAM 1 Monitor and 1 Touchscreen Monitor Swept Source Laser	Same
Laser Type	Swept Source Semiconductor Laser	Swept Source Semiconductor Laser	Same
Imaging element pullback speed	0.5, 1.0, and 2.0 mm/s	0.5, 1.0, and 2.0 mm/s	Same
Pullback Distance	150mm	150mm	Same
Controller Housing	Handle	Handle	Same
Controller User Interface	LCD screen	LCD screen	Same

Performance Testing (Bench):

Biocompatibility
There are no changes to the patient contact materials of the device compared to the predicate (K163345), and therefore no changes to its biocompatibility. The biocompatibility testing reported for the predicate device still applies.

The biocompatibility evaluation of the predicate TVC-C195-42 catheter was conducted for an external communicating device in circulating blood, with a limited contact duration of ≤ 24 hrs. The series of testing was conducted utilizing Good Laboratory Practice (GLP) following ISO 10993 and ASTM standards.

Sterilization and Shelf Life
There are no changes to the device, its packaging, or the sterilization process requiring sterilization re-qualification. The sterilization testing reported for the predicate device (K163345) still applies.

The sterilization qualification for the predicate was conducted using the TVC-C195-42 catheter and packaging. Results reported met the criteria defined in ISO 11135: 2014.

The shelf life of the TVC-C195-42 catheter was re-evaluated to augment the shelf life from 6 to 18 months compared to the predicate (K163345). The TVC-C195-42 passed all catheter and accessory specifications to support an 18-month shelf life.

Performance Testing
There are no changes or modifications that significantly affect the safety or effectiveness of the system compared to the predicate (K163345). The proposed device has the same technological, engineering, and performance specifications. Only minor modifications have been made to the device since the market clearance of the predicate.

Verification and validation testing of the predicate was performed on the catheter, console, controller, and software to demonstrate that the system met all design specifications. All modifications were documented, reviewed, and approved per the Quality System Regulation. Where appropriate, modifications were tested according to verification and validation protocols and results recorded and documented per the Quality Management System.

EMC and Electrical Safety Testing
There are no changes to the device requiring re-evaluation of EMC and Electrical Safety. The EMC and Electrical Safety testing reported for the

predicate device (K163345) still applies. Note: EMC testing per IEC 60601-1-2 was repeated after clearance of the predicate device specifically to satisfy Korean regulatory requirements (i.e. testing at 220VAC/60Hz, CB scheme).

Performance Testing (Animal):

There are no changes to the device requiring *in vivo* animal testing. The animal testing reported for the predicate device (K163345) still applies.

The *in vivo* animal assessment of the predicate device was conducted on swine. There were no safety concerns in the swine coronary artery model after imaging with the TVC-C195-42 catheter. Assessment of the predicate where imaging was performed through an implanted stent to determine apposition and malapposition of the stent met the objectives of the study.

Performance Testing (Clinical):

The proposed change is an expansion of the intended use to include an indication stating "The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events" (see Substantial Equivalence Rationale below). The justification for this label expansion is based on the prospective, multi-center Lipid Rich Plaque (LRP) clinical study.

The overall study objective of the Lipid-Rich Plaque (LRP) Study was to determine in patients undergoing multi-vessel NIRS-IVUS imaging, the relationship between LRPs detected by intracoronary NIRS at non-stenotic sites and the prediction of subsequent coronary events from new culprit lesions at both the patient level (vulnerable patients) and the segment level (vulnerable plaque).

The results satisfied the primary and key secondary endpoints of the LRP Study, demonstrating an independent and statistically significant association between NIRS-identified coronary lipid cores and the occurrence of patient and plaque level major adverse cardiovascular events. There were no statistically significant differences found due to age, race, ethnicity, or sex.

Substantial Equivalence Rationale:

There are no proposed changes to the design, scientific principles of operation, principal technological characteristics, or safety of this product. The non-clinical and clinical testing performed on the proposed device indicates that it is safe and effective, and is substantially equivalent to the predicate device.

The proposal is to expand the indications for use of the device as indicated by the underscoring below:

The Makoto Intravascular Imaging System is intended for the near-infrared examination of coronary arteries in patients undergoing invasive coronary angiography.

a. The System is intended for the detection of lipid-core-containing plaques of interest.
b. The System is intended for the assessment of coronary artery lipid core burden.
c. <u>The System is intended for the identification of patients and plaques at increased risk of major adverse cardiac events</u>.

The System is intended for ultrasound examination of coronary intravascular pathology.

a. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.