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)*
K183599

Device Name
Makoto Intravascular Imaging System™
Dualpro™ IVUS+NIRS Imaging Catheter

Indications for Use *(Describe)*

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.

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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