March 14, 2022

SIS Medical AG
c/o H. Semih Oktay
President
CardioMed Device Consultants, LLC
1783 Forest Drive
Suite 254
Annapolis, Maryland 21401

Re: K212393
Trade/Device Name: OPN NC PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: February 7, 2022
Received: February 8, 2022

Dear H. Semih Oktay:

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/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,

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212393

Device Name

OPN NC PTCA Dilatation Catheter

Indications for Use *(Describe)*

The OPN NC PTCA Dilatation Catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(as required by 21 CFR 807.92)

SIS MEDICAL
Swiss | Interventional | Systems

OPN NC PTCA Dilatation Catheter

510(k) K212393

Date Prepared:	March 4, 2022
Applicant:	SIS Medical AG Hungerbüelstrasse 12a CH-8500 Frauenfeld Switzerland
Contact Name: **Title:** **Email:** **Telephone:** **Fax:**	H. Semih Oktay, PhD President, CardioMed Device Consultants soktay@cardiomedllc.com (410) 271-2088 (410) 674-2133
Trade Name:	OPN NC PTCA Dilatation Catheter
Device Classification:	Class II per 21 CFR §870.5100
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Product Code:	LOX
Predicate Devices:	NC Euphora Rapid Exchange Balloon Dilatation Catheter, K141090

INTENDED USE/INDICATIONS FOR USE:

The OPN NC PTCA Dilatation Catheter is intended for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter is also indicated for post deployment expansion of balloon expandable coronary stents.

DEVICE DESCRIPTION:

The OPN NC PTCA Dilatation Catheter is a sterile, single use, rapid exchange catheter with a distal non-compliant double layer balloon attached to a flexible distal polymer shaft. The balloon is made from Polyamide and is available in

diameters of 1.5, 2.0, 2.5, 3.0, 3.5, 4.0 and 4.5mm and in balloon lengths of 10, 15 and 20mm.

The distal polymer shaft consists of a two coaxial lumens, with one lumen for inflation and the other to enable the use of a guide wire for positioning the catheter. The catheter is compatible with a 0.014" guidewire, which enters at the distal tip of the catheter and exists at the RX port.

The proximal portion of the catheter is formed from a hypotube containing the inflation lumen. At the proximal end, a hub with luer connector is attached to the hypotube, allowing connection to an inflation device. Radiopaque balloon marker bands enable accurate positioning of the device. Shaft markers for brachial and femoral techniques are also in place.

The OPN NC comes in a single useable length of 147cm. The device nominal pressure is 10 atm and the rated burst pressure is 35 atm.

COMPARISON WITH PREDICATE DEVICES:

Comparison of the OPN NC Dilatation Catheter and predicate device show that the technological characteristics of the subject device such as the components, design, materials, sterilization method, shelf life and operating principle are similar to the currently marketed predicate and reference devices. The intended use of the subject device and the predicate are the same.

		Subject	**Predicate**
Name of Device		**OPN NC PTCA Dilatation Catheter**	**NC Euphora Rapid Exchange Balloon Dilatation Catheter**
Manufacturer		SIS Medical AG	Medtronic Inc.
510(k)		K212393	K141090
Indications for Use		Indicated for balloon dilatation of the stenotic portion of the coronary artery or bypass graft for the purpose of improving myocardial perfusion	Indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft for the purpose of improving myocardial perfusion
		The balloon dilatation catheter is also indicated for post-deployment expansion of balloon expandable coronary stents	The balloon dilation catheter is also indicated for post-deployment expansion of balloon expandable stents
Catheter Shaft Characteristics	Device Design	Rapid Exchange PTCA catheter	Rapid Exchange PTCA catheter
	Radiopaque Marker(s)	2 Platinum/Iridium	2 Platinum/Iridium
	Useable Length	147cm	142cm

		Subject	Predicate
Name of Device		**OPN NC PTCA Dilatation Catheter**	**NC Euphora Rapid Exchange Balloon Dilatation Catheter**
Manufacturer		SIS Medical AG	Medtronic Inc.
510(k)		K212393	K141090
Balloon Characteristics	Balloon Diameters	1.5, 2.0, 2.5, 3.0, 3.5, 4.0, and 4.5mm	2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75, 4.00, 4.50 and 5.00mm
	Balloon Lengths	10, 15 and 20mm	6, 8, 12, 15, 20 and 27mm
	Rated Burst Pressure	35atm	20atm
Hydrophilic coating		No	Coating present, type unavailable
Hydrophobic coating		Yes	
Guide catheter compatibility		1.5 – 3.5mm diameter: 6F (0.071" or 1.8mm) 4.0. – 4.5mm diameter: 7F (0.081" or 2.06mm)	Not known
Guidewire compatibility		0.014" (0.36mm)	0.014" (0.36mm)
Sterilization Method		EO	E-beam

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the OPN NC PTCA Dilatation Catheter to determine substantial equivalence. The following testing/assessments were performed:

- Dimensional Verification
- Simulated Use
- Compliance
- Coating Integrity
- Particulate
- Inflation/deflation
- Corrosion
- Abrasion/Puncture resistance
- Lubricity/pinch testing
- Flex/Kink
- Torque
- Tensile Strength
- Rated burst pressure
- In-Stent rated burst pressure
- Balloon fatigue
- In-Stent balloon fatigue
- Radiopacity

The *in vitro* bench tests demonstrated that the OPN NC PTCA Dilatation Catheter met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and has substantially equivalent safety and effectiveness/performance outcomes to the predicate device.

BIOCOMPATIBILITY:

Testing was performed to assess biocompatibility of the OPN NC PTCA Dilatation Catheter. The following tests were performed:

- Cytotoxicity
- Intracutaneous Reactivity
- Complement Activation (SC5b-9)
- Material Mediated Pyrogenicity
- Sensitization
- Hemolysis (Direct and Extract)
- Thrombogenicity
- Acute Systemic Toxicity

The results from the testing performed showed the OPN NC PTCA Dilatation Catheter to be biocompatible.

CONCLUSION:

The OPN NC PTCA Dilatation Catheter has the same intended use and the same or similar technological characteristics such as components, design, materials, and operating principles as the predicate device. Performance data demonstrates that the device functions as intended. The conclusions drawn from the nonclinical tests demonstrate that the OPN NC has substantially equivalent safety and effectiveness/performance outcomes to the legally marketed predicate device.

Therefore, the OPN NC PTCA Dilatation Catheter is substantially equivalent to the predicate device.