February 15, 2023

Sino Medical Sciences Technology Inc.
c/o Semih Oktay
President and CEO
CardioMed Device Consultants, LLC
1783 Forest Drive, #254
Suite 254
Annapolis, Maryland 21401

Re: K223022
Trade/Device Name: SC HONKYTONK PTCA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: January 12, 2023
Received: January 13, 2023

Dear 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 W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.02.15 13:09:55 -05'00'

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)*
K223022

Device Name
SC HONKYTONK PTCA Dilatation Catheter

Indications for Use *(Describe)*
The SC HONKYTONK PTCA Balloon Dilatation Catheter is indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

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.

510(k) Summary

(as required by 21 CFR 807.92)

PTCA Dilatation Catheter

510(k) K223022

Date Prepared:	September 28, 2022
Applicant:	SINO Medical Sciences Technology Inc.
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:	SC HONKYTONK™ PTCA Dilatation Catheter
Device Classification:	Class II per 21 CFR §870.5100
Classification Name:	Catheters, Transluminal Coronary Angioplasty, Percutaneous
Product Code:	LOX
Predicate Devices:	Emerge™ Monorail PTCA Dilatation Catheter,K163174

INTENDED USE/INDICATIONS FOR USE:

The SC HONKYTONK™ PTCA Balloon Dilatation Catheter is indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

DEVICE DESCRIPTION:

The SC HONKYTONK™ PTCA Balloon Dilatation Catheter is a rapid exchange catheter, including a semi-compliance balloon close to the distal tip. The catheter's distal portion is dual lumen and coaxial. The dual lumen includes an outer lumen for balloon inflation, and an inner lumen to allow a ≤0.014 in (0.36 mm) guidewire to facilitate catheter advancement to and through the stenosis that is to be dilated. The proximal portion of the catheter is a single-lumen, stainless steel hypotube that includes a single luer hub for balloon inflation /deflation. The balloon design provides for an inflatable segment of both known diameter and length at recommended pressures. A balloon protective sheath placed over the balloon maintains a low profile. A mandrel is positioned inside the inner lumen to protect catheter patency. The catheter's tapered tip aids advancement to and through the stenosis.

The effective length of the catheter is 145 cm. Radiopaque marker bands, in conjunction with fluoroscopy, are aid for the placement of the catheter's balloon. The 1.50 mm device size has one radiopaque marker band, while all other sizes have two radiopaque marker bands. The entire balloon has a hydrophobic coating. The shaft has a hydrophilic coating from the guidewire port to just distal of the balloon.

COMPARISON WITH PREDICATE DEVICES:

Comparison of the SC HONKYTONK™ PTCA Balloon Dilatation Catheter and predicate device shows 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. The intended use of the subject device and the predicate are the same.

Table 5-1: Comparison of SC HONKYTONK™ PTCA Balloon Dilatation Catheter and Predicate Device

		Subject	Predicate
Name of Device		**SC HONKYTONK™ PTCA Balloon Dilatation Catheter**	**Emerge ™ Monorail PTCA Dilatation Catheter**
Manufacturer		SINO Medical Sciences Technology Inc.	Boston Scientific Corporation
510(k)		TBD	K163174
Indications for Use		The SC HONKYTONK™ PTCA Balloon Dilatation Catheter is indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.	The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (1.20 mm balloon models) are indicated as pre-dilatation catheters in the stenotic portion of a coronary artery or bypass graft stenosis (≥70% stenosis). The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 1.50-4.00 mm) are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00-4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).
Catheter Shaft Characteristic	Device Design	Rapid Exchange PTCA Catheter	Rapid Exchange PTCA Catheter
	Radiopaque Marker(s)	2 Platinum iridium (For ø 2.00-4.00mm)/1 Platinum iridium(For ø 1.50mm)	2 Platinum iridium (For ø 2.00-4.00mm)/1 Platinum iridium(For ø 1.20 and 1.50mm)
	Useable Length	145cm	144cm
Balloon Characteristics	Balloon Diameters	1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.50 and 4.00mm	1.20, 1.50, 2.00, 2.25, 2.50, 2.75, 3.00, 3.25, 3.50, 3.75 and 4.00mm
	Balloon Lengths	9, 12, 15, 20, 25, 30 and 35mm	8, 12, 15, 20 and 30mm
	Rated Burst Pressure	Diameter 1.50 - 3.50 mm, RBP is 14 atm; Diameter 4.00 mm, RBP is 12 atm.	Diameter 1.20 mm, RBP is 18 atm; Diameter 1.50 - 3.25 mm, RBP is 14 atm; Diameter 3.50 - 4.00 mm, RBP is 12 atm.
Hydrophilic coating		Yes	Yes
Hydrophobic coating		Yes	Yes
Guide catheter compatibility		Minimum I.D.=0.056in (1.42mm)	Minimum I.D.=0.056in (1.42mm)
Guidewire compatibility		≤0.014in (0.36 mm)	≤0.014in (0.36 mm)
Sterilization Method		EO Sterilization	EO Sterilization

NON-CLINICAL TESTING/PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the SC HONKYTONK™ PTCA Balloon Dilatation Catheter to determine substantial equivalence. The following testing/assessments were performed:

- Dimensional Verification
- Simulated Use
- Balloon Fatigue
- Inflation/Deflation Time
- Flexibility/Kink
- Radiopacity
- Particulate
- Component Dimensional Compatibility
- Rated Burst Pressure
- Compliance
- Bond Strength (including Tip Pull)
- Torque
- Coating Integrity

The *in vitro* bench tests demonstrated that the SC HONKYTONK™ PTCA Balloon Dilatation Catheter met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the device functions as intended and does not introduce new risks to safety or effectiveness when compared to the predicate device.

BIOCOMPATIBILITY:

Testing was performed to assess biocompatibility of the SC HONKYTONK™ PTCA Balloon Dilatation Catheter. The following tests were performed:

- Cytotoxicity
- Intracutaneous Reactivity
- Complement Activation (SC5b-9)
- Material Mediated Pyrogenicity
- Partial Thromboplastin Time
- Sensitization
- Hemolysis (Direct and Extract)
- Thrombogenicity
- Acute Systemic Toxicity
- Heparinized Blood Platelet and Leukocyte Count Assay

The results from the testing performed showed the SC HONKYTONK™ PTCA Balloon Dilatation Catheter to be biocompatible.

CONCLUSION:

The SC HONKYTONK™ PTCA Balloon 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 SC HONKYTONK™ PTCA Balloon Dilatation Catheter does not introduce new risks to safety or effectiveness when compared to the predicate device.

Therefore, the SC HONKYTONK™ PTCA Balloon Dilatation Catheter is substantially equivalent to the predicate device.