December 9, 2022

Fuji Systems Corporation
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K223275
Trade/Device Name: CELLO II Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 26, 2022
Received: November 28, 2022

Dear Prithul Bom:

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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
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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)*
K223275

Device Name

CELLO II Balloon Guide Catheter

Indications for Use *(Describe)*

The CELLO II Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic 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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CELLO II Balloon Guide Catheter

510(k) Summary K223275

Device Trade Name:	CELLO II Balloon Guide Catheter
Model Number:	1650908, 1650909, 1651008, 1651009
Classification:	Class II
Classification Name:	Percutaneous Catheter
Regulation Number:	870.1250
Product Code:	QJP, DQY
Submitter:	Fuji Systems Corporation 200-2, Aza-Ohira, Odakura, Nishigo, Nishi Shirakawa Gun, Fukushima 961-8061 Japan TEL: +81-248-25-4501 FAX: +81-248-25-3779
Contact:	Yoshiyuki Suzuki Regulatory Affairs Manager
Date of Preparation:	November 16, 2022
Predicate Device:	CELLO Balloon Guide Catheter (K120781)

Device Description

The CELLO II Balloon Guide Catheter is a coaxial-lumen, braid-reinforced, variable stiffness catheter with one radiopaque ring marker on the distal end of the balloon and a bifurcated Luer hub on the proximal end. A compliant urethane balloon is mounted on the distal end. Balloon Guide Catheter dimensions and recommended balloon volumes are indicated on the product label. Each catheter is supplied with inserters, a Y-Connector, 3-way stopcocks and syringes.

The CELLO II Balloon Guide Catheters are intended for use in hospitals or other health care facilities which are equipped with trained personnel and specialized equipment to perform peripheral and neurovascular procedures.

The CELLO II Balloon Guide Catheter is intended for facilitating the insertion and guidance of intravascular catheters into selected blood vessels in the peripheral and neuro vasculature systems. The tip of the catheter features a balloon of urethane rubber. Radiopaque ring marker identifies the distal end of the balloon. The shaft is a dual lumen type with coaxial structure featuring a built-in braided stainless steel coil.

The materials of construction are similar to those used in many other similar catheters. The shaft is made of polyurethane, polyamide, stainless steel, and fluorine resin; the balloon is made of urethane. Patient contact is of limited duration, less than 24 hours.

Indications for use

The CELLO II Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Comparison of Technological Characteristics to the Predicate

Device	***Proposed K223275***	***Predicate K120781***	***Consideration***
Manufacturer	Fuji Systems Corporation	Fuji Systems Corporation	Same
Device Name	CELLO II Balloon Guide Catheter	CELLO Balloon Guide Catheter	Similar name
510(k) No.	K223275	K120781	(N/A)
Classification	Class II	Class II	Same
Regulation No.	21 CFR 870.1250	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Percutaneous Catheter	Same
Product Code	QJP, DQY	DQY	Same
Anatomical Sites	Peripheral and neuro vasculature	Peripheral and neuro vasculature	Same
Intended Patient Population	Patients undergoing percutaneous interventional procedures	Patients undergoing percutaneous interventional procedures	Same
Device Description*	The CELLO II Balloon Guide Catheter is a ✓ coaxial-lumen, braid-reinforced, variable stiffness catheter with ✓ one radiopaque ring marker on the distal end of the balloon ✓ and a bifurcated Luer hub on the proximal end. ✓ A compliant urethane balloon is mounted on the distal end. Balloon Guide Catheter dimensions and the recommended balloon inflation volumes are indicated on the product label.	The CELLO Balloon Guide Catheter is a ✓ coaxial-lumen, braid-reinforced, variable stiffness catheter with ✓ two radiopaque markers on both the distal and proximal ends of the balloon ✓ and a bifurcated Luer hub on the proximal end. ✓ A compliant silicone balloon is mounted on the distal end. Balloon Guide Catheter dimensions and the recommended balloon inflation volumes are indicated on the product label.	Similar technological characteristics, minor differences do not raise new questions of safety and effectiveness.

Comparison of Technological Characteristics to the Predicate (continued).

Device	***Proposed K223275***	***Predicate K120781***	***Consideration***
Indications for use	The CELLO II Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vessel in the peripheral and neuro vasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.	Same
Product Code	1650908, 1650909, 1651008, 1651009	1610560, 1610570, 1610580, 1610590	(N/A)
Size	8F, 9F	6F, 7F, 8F, 9F	8F and 9F are same
Labeled Shaft Outer Diameter	8F: 2.67 mm 9F: 3.00 mm	8F: 2.60 mm 9F: 3.00 mm	Similar, minor differences do not raise new questions of safety and effectiveness.
Labeled Shaft Inner Diameter	8F: 2.16 mm 9F: 2.32 mm	8F: 1.90 mm 9F: 2.15 mm	Similar, minor differences do not raise new questions of safety and effectiveness.
Effective length	90 cm and 100 cm	92 cm to 102 cm	Similar, minor differences do not raise new questions of safety and effectiveness.

Comparison of Technological Characteristics to the Predicate (continued).

Device	***Proposed K223275***	***Predicate K120781***	***Consideration***
Tip Shape	Straight	Straight	Same
Coating	None	None	Same
Material/Shaft	Polyurethane, Polyamide, Stainless steel, Fluorine resin	Polyurethane, Polyamide, Stainless steel, Fluorine resin	Same
Material/Balloon	Urethane rubber	Silicone rubber	Similar technology, material differences do not raise new questions of safety and effectiveness, both materials are used for compliant balloons for intravascular use
Accessories Supplied	Inserters, Y-Connector, 3-way stopcock, Syringe	Dilator, Inserter	Similar, the differences do not raise new questions of safety and effectiveness.
Sterilization	Ethylene oxide	Ethylene oxide	Same
Sterility Assurance Level	SAL=10^{-6}	SAL=10^{-6}	Same

Nonclinical Tests: CELLO II Balloon Guide Catheter

Test	***Results***	***Conclusion***
Surface	Free from extraneous matter, process and surface defects.	Pass
Force at Break	Tip and all joints meet reliability/confidence requirements in statistical confidence limits test.	Pass
Freedom from Leakage	Shall not leak liquid when pressurized per methods in ISO 10555-1, Annex C. Shall not leak air when aspirated per methods in ISO 10555-1, Annex D.	Pass
Tip Configuration	Distal tip smooth, rounded, tapered or similarly finished.	Pass
Hubs	Comply with ISO 80369-7.	Pass
Freedom from Leakage and Damage upon Inflation	No leakage or evidence of damage, such as herniation or bursting of the shaft or balloon.	Pass
Dimensional Verification	All dimensions meet reliability/confidence requirements in statistical confidence limits test.	Pass
Balloon Preparation, Deployment and Retraction	Catheters can be advanced to intended sites within a tortuous 3D vessel model where other devices can be deployed distally and retracted; all devices could be retracted without damage.	Pass
Balloon Rated Burst Volume	All balloons met reliability/confidence requirements in statistical confidence limits test.	Pass
Balloon Fatigue	All balloons withstand 20 cycles of inflation.	Pass
Balloon Compliance	All balloons have predictable change in size with volume of contrast solution.	FIO*
Balloon Inflation-Deflation Time	All balloons inflate and deflate predictably.	FIO*
Flexibility and Kink	All catheters meet reliability/confidence requirements in statistical confidence limits test.	Pass
Torque Strength	All models can be torqued at least 135° when the distal tip is fixed in a tortuous 3D vessel model.	FIO*
Radiopacity	Radiopaque markers are visible during angiography under a variety of conditions.	FIO*
Particulate testing	All catheters meet the particle generation criteria and exhibit similar size and quantity of particulates in comparison to the predicate device.	Pass
Tip Flexibility	The tips of catheters meet the tip flexibility criteria.	Pass
Contrast Agent Durability	There was no damage after application of pressure of 300 PSI.	Pass

* For Information Only

Nonclinical Tests: Y-Connector

Test	*Results*	*Conclusion*
Hubs	Comply with ISO 80369-7.	Pass

Biocompatibility: CELLO II Balloon Guide Catheters

Endpoint	*Test*	*Results*	*Conclusion*
Cytotoxicity	ISO 10993-5:2009 L929 MEM Elution Test	Non-Cytotoxic	Pass
Sensitization	ISO10993-10:2010 Guinea Pig Maximization Test	Non-Sensitizing	Pass
Irritation/Intracutaneous Reactivity	ISO10993-10:2010 Intracutaneous Injection Test	Non-Irritant	Pass
Acute Systemic Toxicity	ISO10993-11:2017 Systemic Injection Test	No Acute Toxicity	Pass
Material-Mediated Pyrogenicity	ISO10993-11:2017 Rabbit Pyrogen Test	Non-Pyrogenic	Pass
Hemocompatibility	ASTM F756-17 Hemolysis-Rabbit Blood (Direct and Indirect contact)	Non-Hemolytic	Pass
	ASTM F2382-18 Partial Thromboplastin Time Test (Direct contact)	Hemocompatible	Pass
	ISO10993-4:2017 Platelet and leukocyte Binding- (Direct contact)	Hemocompatible	Pass
	ISO10993-4:2017 Complement Activation Assay (Direct contact)	Non-Complement Activation	Pass
	ISO10993-4:2017 Thrombogenicity Study in Dog	Non-Thrombogenic	Pass

Biocompatibility: Y-Connector

Endpoint	***Test***	***Results***	***Conclusion***
Cytotoxicity	ISO 10993-5:2009 L929 MEM Elution Test	Non-Cytotoxic	Pass
Sensitization	ISO10993-10:2010 Guinea Pig Maximization Test	Non-Sensitizing	Pass
Irritation/Intracutaneous Reactivity	ISO10993-10:2010 Intracutaneous Injection Test	Non-Irritant	Pass
Acute Systemic Toxicity	ISO10993-11:2017 Systemic Injection Test	No Acute Toxicity	Pass
Material-Mediated Pyrogenicity	ISO10993-11:2017 Rabbit Pyrogen Test	Non-Pyrogenic	Pass
Hemocompatibility	ASTM F756-17 Hemolysis-Rabbit Blood (Direct and Indirect contact)	Non-Hemolytic	Pass

Clinical Tests

No clinical testing was deemed necessary to support this premarket notification.

Conclusions

The conclusions drawn from the nonclinical tests demonstrate that the CELLO II Balloon Guide Catheter is substantially equivalent to the legally marketed predicate device.

The design of the CELLO II Balloon Guide Catheter is similar to that of the predicate: each catheter shaft includes an internal stainless steel braid surrounded by polymer. The balloon is made from urethane rubber and its position can be identified during angiography because of radiopaque markers. Although the material of the balloon is different from the predicate, the results of each balloon non-clinical tests confirmed that the subject device is substantially equivalent to the predicate.

The indications for use of the CELLO II Balloon Guide Catheter are the same as that of the predicate.

The patient population of the CELLO II Balloon Guide Catheter is the same as that of the predicate.

The CELLO II Balloon Guide Catheter is intended for use in the same anatomical sites as the predicate.