IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RESPONSE TO OFFICE ACTION DATED JULY 8, 2019

This is in response to the Office Action dated July 8, 2019, wherein the Office refused the pending Application Serial No. 88/396,362 for the mark CELLO ("Applicant's Mark") based on a likelihood of confusion with U.S. Registration No. 4,113,601 for the mark CELLO ("Registrant's Mark" or "Identified Registration"). The Examining Attorney also indicated that that the identification of goods should be amended. Applicant submits the following response in support of registration of the mark CELLO.

I. CONFUSION BETWEEN APPLICANT'S MARK AND THE REGISTRANT'S MARK IS NOT LIKELY

Applicant respectfully disagrees with the Office's assessment that there may be a likelihood of confusion between Applicant's Mark and the Registrant's Mark. The relevant factors in determining whether a likelihood of confusion exists were set forth in *In re Application of E.I. Dupont de Nemours & Co.*, 177 U.S.P.Q. 563 (C.C.P.A. 1973). Not all of the Dupont factors are, however, relevant to every case, and even one factor may be dispositive on the question of likelihood of confusion. Id. at 567; see also *In re Coors Brewing Co.*, 68 U.S.P.Q. 2d 1059 (Fed. Cir. 2003). The relevant factors, here, namely the dissimilarity of the parties' goods, the dissimilarity of established, likely to continue, trade channels, and the fact that both parties' products are purchased and used by highly sophisticated consumers make clear that confusion between the parties' marks is very unlikely.

In fact, the Applicant's Mark identifies veterinary dentistry as an industry specific limitation and its goods would not be marketed or sold to the customers of the Registrant's Mark. Registrant's Mark is also limited to specific goods in a specialized, highly regulated industry, medical catheters. It is unlikely that medical or veterinary professionals would confuse two unrelated products.

A. There are Critical Differences between the Parties' Products and Their Trade Channels Which Make Confusion Unlikely

In determining likelihood of confusion, the goods covered in Applicant's Application, should be compared with those set forth in the Registered Mark. TMEP §1207.01(a)(iii) (7th ed., October 2010); *In re Trackmobile, Inc.*, 15 U.S.P.Q. 2d 1152, 1153 (T.T.A.B. 1990). Where the parties' respective goods are sufficiently distinct, there will be no likelihood of confusion. *See, e.g., Allstate Ins. Co. v. Allstate Inv. Corp.*, 136 U.S.P.Q. 156 (W.D. La. 1962), aff'd, 141 U.S.P.Q. 280 (5th Cir. 1964) (no likelihood of confusion between ALLSTATE for insurance services and ALLSTATE for mortgage brokerage services).

The Trademark Trial and Appeal Board, and the courts have repeatedly determined that the use of identical marks on goods or services do not cause confusion even when the goods are much more closely related than Applicant's goods and the goods in the Identified Registration. *See, e.g., In re Mars, Inc.*, 222 U.S.P.Q. 938, (Fed. Cir. 1984) (no likelihood of confusion between CANYON for candy bars and CANYON for fresh citrus fruit); *J.C. Penney Co., Inc. v. Arctic Enter., Inc.*, 183 U.S.P.Q. 342 (D.C. Minn. 1974) (no likelihood of confusion between the mark EL TIGRE for snowmobiles, and the mark EL TIGRE for automobile tires and mini-bikes); *In re Sydel Lingerie Co., Inc.*, 197 U.S.P.Q. 629 (T.T.A.B. 1977) (no likelihood of confusion between the mark BOTTOMS UP for ladies' and children's underwear, and the mark BOTTOMS UP for men's suits, coats and trousers).

Here, the Registrant's Mark is registered for, "Medical catheter." Emphasis added. Applicant's goods are dental instruments for use in veterinary applications; dental instruments, namely, suction tools, handpieces for use with rotating attachments for dental applications, dental scalers, lights attached to dental apparatus for use with dental treatment, dental syringes, water supply for dental applications; portable dental treatment system including dental instruments, namely, suction tools, handpieces for use with rotating attachments for dental applications, dental scalers, lights attached to dental apparatus for use with dental treatment, dental syringes, water supply for dental applications. Applicant's goods are expressly limited to veterinary dentistry.

Accordingly, the identifications at issue explicitly describe the goods that are used in very different medical fields that do not overlap. The Registrant's website bears out the description of the catheter, as shown in the attached Appendix A. In sharp contrast with a medical catheter, Applicant's products are specifically limited to veterinary applications in dentistry to be used by doctors of veterinary medicine, as shown in the attached Appendix B.

The Office simply argues that the marks "have the potential to be used…in exactly the same manner." However, this is not legally or functionally possible. Registrant's medical catheters are not used for veterinary applications and are highly regulated by the Food and Drug Administration ("FDA"). Conversely, Applicant's products cannot be used for human medical procedures as they are not regulated or approved by the (FDA) for such use. Indeed, the FDA has very different standards for animal medical devices and human medical devices. See https://www.fda.gov/animal-veterinary/animal-health-literacy/how-fda-regulates-animal-devices, a printout of which is provided in attached Appendix C. Federal laws and regulations, restrict the use of Registrant's and Applicant's products, and as such these products **cannot** be used in "exactly the same manner" as purported by the Office.

The Office also states that "because [the marks] are identical, these marks are likely to engender the same connation and overall commercial impression when considered in connection with applicant's and registrant's respective goods." However, Applicant's and Registrant's goods are so distinct confusion is highly unlikely. Indeed, Registrant's goods are medical catheters that are not used in veterinary dental procedures. Applicant's veterinary dental products cannot, as a matter of law and fact, be used in place of Registrant's products.

B. The Careful Conditions Under Which Applicant's Goods are Purchased and the Sophistication of Applicant's Customers Make Confusion Unlikely

It is well settled that when the relevant buyer class is composed solely of professionals or commercial buyers familiar with the field, they are sophisticated enough not to be confused, even by trademarks that are closely similar or identical. The Trademark Trial and Appeal Board has consistently determined that sophisticated buyers of medical instruments expected to exercise care in selection of such products and not likely to be confused by use of similar marks. *Hewlett*

Packard Co. v. Human Performance Measurement, Inc., 23 U.S.P.Q. 2d 1390 (T.T.A.B. 1991); *see also ArrowFastener Co., v. Stanley Works*, 35 U.S.P.Q.2d 1449 (2d Cir. 1995) (buyers of defendant's $400 pneumatic stapler gun used for building construction and furniture manufacture utilize their expertise in selecting defendant's stapler and are not likely to be confused); and *McGraw-Hill, Inc. v. Comstock Partners, Inc.*, 17 U.S.P.Q. 2d 1599 (Fed. Cir. 1990) (purchasers of closed end investment fund and publically traded stocks considered sophisticated and discriminating purchasers).

Accordingly, confusion rarely, if ever, occurs where the services marketed are highly specialized and the target consumers are experts required to make well-informed purchasing decisions. Such purchasers exercise their expertise and conduct suitability analyses to determine whether the products under consideration will be appropriate for the intended specialized purpose. *See, e.g., In re NeoPhotonics Corp.*, Ser. No. 78-331,853, http://des.uspto.gov/FoiafTTABReadingRoom.jsp (T.T.A.B. 2008) (not precedential).

Further, the products are sold in very different trade channels and contexts. Registrant's products are marketed to doctors and health clinics, and are only available from highly sophisticated medical distributors. As shown in the attached Appendix A. In contrast, the Applicant's products are marketed to veterinarians and are sold directly from the manufacturer to the veterinary establishment. Nether product is sold to the public at large. Indeed, they are both sold to medical professionals who are highly educated and must carefully source medical devices. Moreover, a review of the Applicant's websites reveals that the Applicant advertises its products specifically at veterinary tradeshows. Registrant utilizes highly specialized medical device distributors to sell its products.

Accordingly, there is no overlap between the target customers of each product.

The Office alludes that even sophisticated consumers are not immune from source confusion. However, in this case, the sophisticated consumers are different classes of consumers (human medical professionals and veterinary medical professionals), each seeking different medical devices to treat vastly different issues. Moreover, it is well recognized in both fields of medicine that the presence of a catheter makes the performance of dental treatment very risky for

infections. The likelihood of confusion based on the name of a good in this matter is highly unlikely.

Accordingly, such sophistication and care in purchasing will eliminate the likelihood of confusion and is therefore relevant here where confusion is already unlikely due to the substantial distinctions in the products.

II. LIMITATION OF GOODS

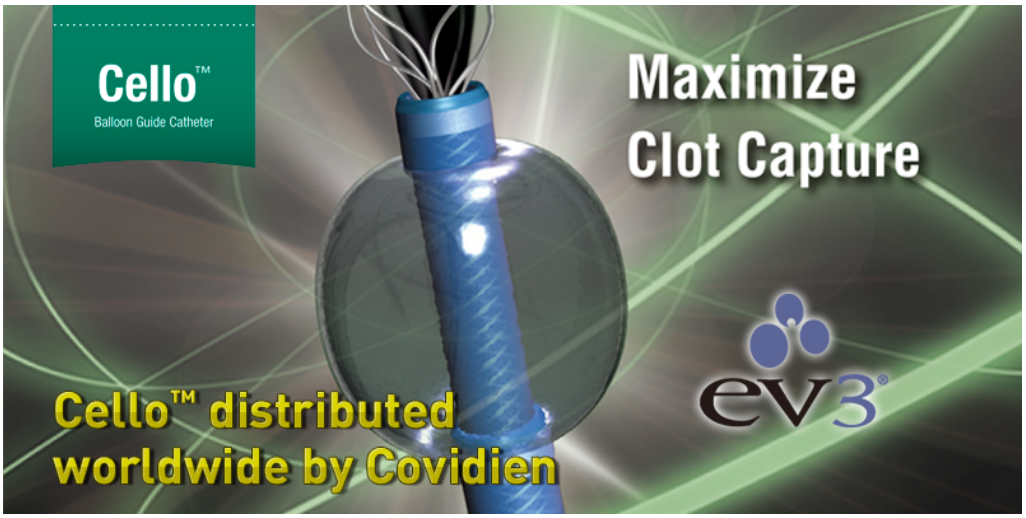
Applicant has further amended the identification of goods to exclude catheters from its description of goods to further ensure there is no possible likelihood of confusion.

III. CONCLUSION

A substantial likelihood that the public will be confused must be shown in order for an application to be rejected on the grounds of likelihood of confusion. In view of the significant differences between the parties' goods and trade channels, along with the sophistication of Applicant's purchasers (as well as Registrant’s customers), confusion is not likely. Accordingly, Applicant requests that the Applicant’s Mark be advanced to publication.

Appendix A

CELLO



Improve proximal flow arrest and aspiration during clot rettieval

Maximize aspiration

- Large lumen catheter ensures high aspriration.
- Designed to reduce ovalization, Cello contains braiding in both inner and outer layers intended to enhance structural integrity

MInimize vessel wall contact

- The CelloTM Balloon Guide Catheter is designed to minimize vessel well contact during flow occlusion.

Maximize aspiration

- Overlapping braided tubes provide kink resistance and strong support for device delivery
- Two marker bands for device visibility and placement

COVIDIEN ev3 Covidien Neurovascular
http://www.ev3.net/neuro/intl/guide-catheters/cellotrade-balloon-guide-catheter.htm

Specifications

Cello Balloon Guide Catheter Ordering Information

Reference No.	Product Name	Conformable Sheath	Tip Length (mm)	Balloon Length (mm)	I.D.mm (in)	Effective Length (cm)	Total Length (cm)
1610060	Cello 6F+	7F	3	7	1.30 (0.051 in)	95	103
1610070	Cello 7F+	8F			1.70 (0.067 in)	95	103
1610080	Cello 8F	8F		10	1.90 (0.075 in)	95	103
1610090	Cello 9F	9F			2.15 (0.085 in)	92	100

Anesthesiology

TCB UNIVENT
UNIBLOCKER
SILBRONCHO
Wire Reinforced Endotracheal Tube
Tracheostomy Tube with Cuff (GB type)

Interventional Radiology

CELLO
MASAMUNE
IIGUMAN

Cardiac Surgery

Retro-TH Catheter
SPF CATHETER
SP-GRIPFLOW
IC OCCLUDER
AP-GRIPFLOW
MiniShunt

Neuro Surgery

Flushing Device Ventricular Tube (STANDARD / FLAT BOTTOM TUBE)
Flushing Device Ventricular Tube (FLAT BOTTOM K TYPE / DOUBLE CHAMBAR TYPE)
PERITONEAL TUBE
L-P Shunt Set
L-P Shunt Set Combined Type
Ventricular Drainage Tube
Ventricular Drainage Set 2
SERECEET
Cerebrospinal Fluid Reservoir AT / BT
Cerebrospinal Fluid Reservoir CT / DT
CONNECTOR

Solitaire FR Revascularization Device Information

Reference No.	Size (mm)	Recommended Vessel Diameter (mm)	Push Wire Length (cm)	Minimum Microcatheter ID (in)	Distal Markers	Proximal Markers
SRD-4-15	4 X 15	2.0 - 4.0	180	0.021	3	1
SRD-4-20	4 X 20					
SRD-6-20	6 X 20	3.0 - 5.5		0.027	4	
SRD-6-30	6 X 30					

Urology

- SELFCATH
- FOLEY 2-WAY PEDIATRIC

Enteral Access

- ILEUS TUBE SET WING TIP CONTROL
- ILEUS TUBE SET BALLOON CONTROL
- ILEUS TUBE SET SINGLE BALLOON / DOUBLE BALLOON

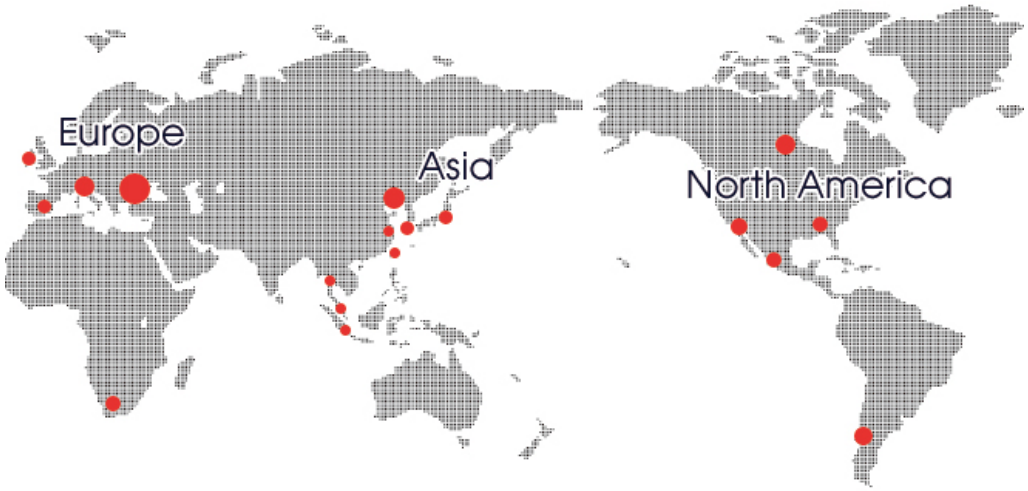
P.E.G.

- GB Gastrostomy Balloon Catheter
- GB Gastrostomy Balloon Button
- GB Gastrostomy Balloon Catheter Kit
- GB Gastrostomy Balloon Button Kit

Others

- SENGSTAKEN BLAKEMORE
- TREX

Distributors



Europe

Europe

Covidien Neurovascular

Products

Cello™

http://www.ev3.net/neuro/intl/guide-catheters/cellotrade-balloon-guide-catheter.htm

North America

USA

Ambu

http://www.ambuusa.com/

Products

Fuji One Lung Ventilation products

Covidien Neurovascular

Products

Cello™

Canada

Ambu

http://www.ambuusa.com/

Products

Fuji One Lung Ventilation products

Asia

Products

- Anesthesiology
- Interventional Radiology
- Cardiac Surgery
- Neuro Surgery
- Urology
- Enteral Access
- P.E.G.
- Others

Distributors

- Europe
- North America
- Asia
- Other Countries

About Us

- President Greeting
- Profile
- Quality System

South Korea	Solvit Medical Inc.	Products Cello™
China	 HighChem Co., LTD http://www.highchem.us/	Products Fuji One Lung Ventilation products
Taiwan	 BIOTRONIC INSTRUMENT ENTERPRISE LTD. http://www.airwaydevices.com.tw/	Products Fuji One Lung Ventilation products
Indonesia	PT NITRA	Products Neuro Surgery
Thailand	 MEDITOP CO., LTD. http://www.meditopthailand.com/	Products Urology

Other Countries

Other Countries	 Please contact us. salesitl@fujisys.co.jp	

CELLO™, Balloon Guide Catheter 1510570

GUDID 04544050093460

The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vess

FUJI SYSTEMS CORPORATION

Vascular guide-catheter, single-use

Primary Device ID	04544050093460
NIH Device Record Key	90ea7ea8-c45f-465b-92af-8f7c7a2d0fb5
Commercial Distribution Status	In Commercial Distribution
Brand Name	CELLO™, Balloon Guide Catheter
Version Model Number	7F
Catalog Number	1510570
Company DUNS	715919973
Company Name	FUJI SYSTEMS CORPORATION
Device Count	1
DM Exempt	false
Pre-market Exempt	false
MRI Safety Status	MR Unsafe

Human Cell/Tissue Product	false
Device Kit	false
Device Combination Product	false
Single Use	true
Lot Batch	true
Serial Number	true
Manufacturing Date	false
Expiration Date	true
Donation Id Number	true
Contains Natural Rubber Latex	false
Labeled No Natural Rubber Latex	false
RX Perscription	true
OTC Over-The-Counter	false

Customer Support Contacts

Phone	949-837-3700
Email	XX@XX.XX (mailto:XX@XX.XX)

Device Identifiers

Device Issuing Agency	Device ID
GS1	04544050093460 [Primary]

FDA Pre-market Approvals/Notifications & deNovo

Premarket Notification: K120781 (/PMN/K120781)

FDA Product Code

DQY (/Product-Code/DQY)	Catheter, Percutaneous

Sterilization

Steralize Prior To Use	false
Device Is Sterile	true

Device Entry Metadata

Public Version Status	Update
Device Record Status	Published
Public Version Number	5
Public Version Date	2019-01-23
Device Publish Date	2015-09-24

On-Brand Devices [CELLO™, Balloon Guide Catheter]

04544050093491 (/GUDID/04544050093491)	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vess
04544050093484 (/GUDID/04544050093484)	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vess
04544050093460 (/GUDID/04544050093460)	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vess
04544050093446 (/GUDID/04544050093446)	The CELLO Balloon Guide Catheter is indicated for use in facilitating the insertion and guidance of intravascular catheters into a selected blood vess

510(k) Summary, K120781

AUG 9 2012

Manufacturer
Fuji Systems Corporation
23-14, Hongo 3-Chome, Bunkyo, Tokyo
113-0033 Japan
Phone: +81-5489-1915

Contact
Yoshihiko Semba
General Manager, Director
International Division

Date of Preparation
July 25, 2012

Product Names

Generic Name	*Classification*	*Product Code*	*Trade Name*	*Model No.*
Percutaneous Catheter	21 CFR 870.1250 Class II	DQY	CELLO Balloon Guide Catheter	1610560 (6 F)
				1610561 (6 F)
				1610570 (7 F)
				1610571 (7 F)
				1610580 (8 F)
				1610590 (9 F)

Predicate Device
Concentric Balloon Guide Catheter, K021899

Device Description

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 recommended inflation volumes are indicated on the product label. Each catheter is supplied with an appropriately-size Dilator.

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

The CELLO Balloon Guide Catheter is used for facilitating the insertion and guidance of intravascular catheters into selected blood vessels in the peripheral and neurovasculature. The tip of the catheter features a balloon of silicone rubber. Radiopaque markers identify the proximal and distal ends 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 resemble those used in many other similar catheters. The shaft is made of polyurethane, polyamide, stainless steel and PFA; the balloon is silicone. Patient contact is of limited duration, less than 24 hrs.

Intended Use

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 neurovasculature systems. The balloon provides temporary vascular occlusion during these and other angiographic procedures.

Comparison of Technological Characteristics, compared to the Predicate

Device	***Proposed***	***Predicate***	***Consideration***
Device Name	CELLO Balloon Guide Catheter	Concentric Balloon Guide Catheter	(N/A)
Device Description*	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 product label. A dilator is provided with each catheter.	Concentric and Merci Balloon Guide catheters are coaxial lumen, braid-reinforced, variable stiffness catheters with a radiopaque marker on the distal end and a bifurcated luer hub on the proximal end. A compliant balloon is flush mounted on the distal end. Balloon Guide catheter dimensions and maximum recommended balloon inflation volume are indicated on product label. If indicated on product label, a dilator is provided.	Similar technological characteristics
Size	6F, 7F, 8F, 9F	8F, 9F	8F and 9F are the same
Effective length	920 mm to 1020 mm	800 to 950	Overlap from 920 to 950 mm
Material/Shaft	Polyurethane, Polyamide, Stainless steel, PFA	Polyurethane, Stainless steel	Similar materials
Material/Balloon	Silicone rubber	Silicone rubber	Same
Sterilization	Ethylene oxide	Ethylene oxide	Same

*Verbatim from each device's IFU.

Nonclinical Tests, CELLO Balloon Guide Catheters

Test	*Results*	*Conclusion*
Surface	Free from extraneous matter, process and surface defects.	Pass
Force at Break	All joints meet reliability/confidence requirements in statistical confidence limits test	Pass
Freedom from Leakage	Shall not leak liquid when inflated. Air shall not leak into the hub during aspiration.	Pass
Tip Configuration	Distal tip smooth, rounded, tapered or similarly finished.	Pass
Hubs	Comply with ISO 594-1 and ISO 594-2	Pass
Freedom from Leakage and Damage on 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 realistic tortuous path model where other devices can be deployed distally and retracted; all devices could be retracted without damage	Pass
Balloon Rated Burst Pressure (RBP)	All balloons meet 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 pressure	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 180° when the distal tip is fixed in a tortuous path model	FIO*
Radiopacity	Radiopaque markers are visible during angiography under a variety of conditions	FIO*

* For Information Only

Nonclinical Tests, Dilator

Test	*Results*	*Conclusion*
Surface	Free from extraneous matter, process and surface defects.	Pass
Force at Break	All joints meet reliability/confidence requirements in statistical confidence limits test	Pass
Freedom from Leakage	Shall not leak liquid when inflated. Air shall not leak into the hub during aspiration.	Pass
Tip Configuration	Distal tip smooth, rounded, tapered or similarly finished.	Pass
Hubs	Comply with ISO 594-1 and ISO 594-2	Pass
Freedom from Leakage and Damage on Inflation	No leakage or evidence of damage, such as herniation or bursting of the shaft or balloon.	Pass

Biocompatibility, CELLO Balloon Guide Catheters

Test	*Results*	*Conclusion*
L29 MEM Elution Test-ISO	Non-Cytotoxic	Pass
Kligman Maximization Test	No Sensitization	Pass
Intracutaneous Injection Test	Non-irritant	Pass
Systemic Injection Test-ISO	No acute toxicity	Pass
Rabbit Pyrogen Test (Material Mediated)-ISO	Non-pyrogenic	Pass
Hemolysis- Direct Contact	Non-hemolytic	Pass
Hemolysis-Rabbit Blood—ASTM Indirect Contact	Non-hemolytic	Pass
Complement Activation—Direct Contact	Non-Complement Activation	Pass
Complement Activation Assay—ISO Indirect Contact	Non-Complement Activation	Pass
In-vivo Thrombogenicity	Patent vessels No thrombus	Better thrombo-resistance than control

Biocompatibility, Dilator

Test	*Results*	*Conclusion*
L29 MEM Elution Test-ISO	Non-Cytotoxic	Pass
Kligman Maximization Test	No Sensitization	Pass
Intracutaneous Injection Test	Non-Irritant	Pass
Systemic Injection Test-ISO	No acute toxicity	Pass
Rabbit Pyrogen Test (Material Mediated)-ISO	Non-pyrogenic	Pass
Hemolysis- Direct Contact	Non-hemolytic	Pass
Hemolysis-Rabbit Blood—ASTM Indirect Contact	Non-hemolytic	Pass
Complement Activation—Direct Contact	Non-Complement Activation	Pass
Complement Activation Assay—ISO Indirect Contact	Non-Complement Activation	Pass
In-vivo Thrombogenicity	Less thrombus than control	Better thrombo-resistance than control

Clinical Tests

No clinical testing was submitted to support this premarket notification.

Conclusions

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

The design of the CELLO Balloon Guide catheter resembles that of the predicate with regard to its principle of operation: each catheter shaft includes an internal stainless steel braid surrounded by polymer. The balloon is made from silicone rubber and its position can be identified during angiography because of radiopaque markers.

The intended use of the CELLO Balloon Guide Catheter is substantially equivalent to that of the predicate.

The patient population of the CELLO Balloon Guide Catheter is substantially equivalent to that of the predicate.

The CELLO Balloon Guide Catheter is substantially equivalent to the predicate device with respect to the anatomical sites where the device is used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 9 2012

Fuji Systems Corporation
c/o Paul Mason, PhD
Consultant
3250 Second Avenue
San Diego, CA 92103

Re: K120781
CELLO Balloon Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: July 26, 2012
Received: July, 27, 2012

Dear Dr. Mason:

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. 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.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): K120781

Device Name: CELLO Balloon Guide Catheter

Indications for Use:

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

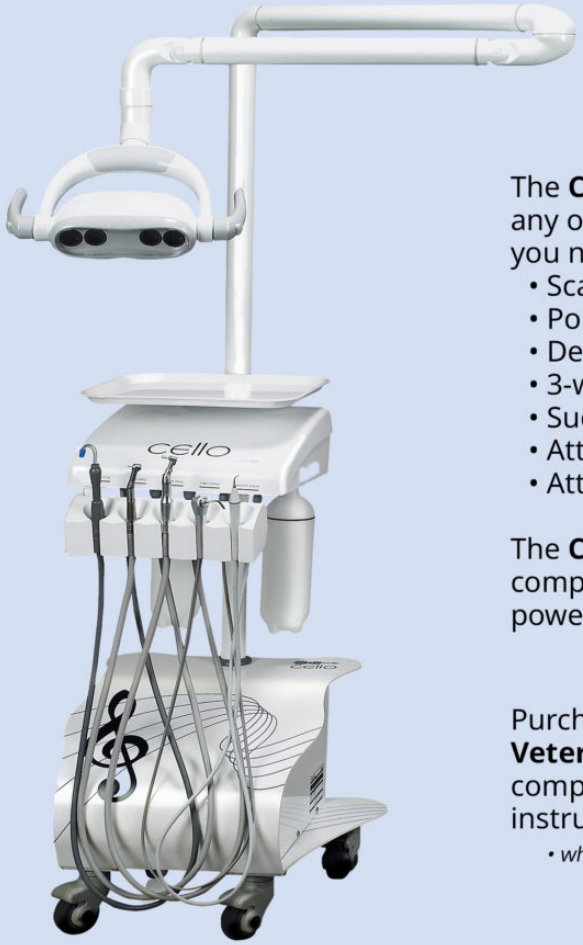
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120781

Appendix B

Introducing the Dental Focus™, LLC

Cello



The **Cello** is a high speed unit unlike any other. The **Cello** has everything you need.

- Scaler
- Polisher
- Dental drill
- 3-way syringe
- Suction
- Attached mayo tray
- Attached powerful light source

The **Cello** has a low-noise, oilless compressor that delivers adjustable power fit to the practioners needs.

Purchase now and bundle our **Veterinary Dental Starter Kit**, complete with high speed burs and instruments.

- *while suplies last*

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Upcoming Events

VMX 2020- Orlando, FL

- January 18-22 (Exhibits 19 -22)
- Orange County Convention Center
- Booth #2102

WVC 2020- Las Vegas, NV

- February 15-19 (Exhibits 16-19)
- Mandalay Bay Convention Center
- Booth #4826

NJVMA 2020- New Brunswick, NJ

- May 15 -17 (Exhibit 16)
- New Brunswick Hyatt
- Table #

WDV Vet 2020– National Harbor, MD

- June 18-20 (Exhibits 19 -20)
- Gaylord Convention Center
- Booth #308

AVMA 2020- San Diego, CA

- July 31- August 4 (Exhibits August 2-4)
- San Diego Convention Center
- Booth #1311

AAFP 2020- Minneapolis, MN

- October 1-4 (Exhibits October 2-4)
- Minneapolis Convention Center
- Booth #TBD

VDF 2020- Dallas, TX

- October 29-November 1 (Exhibits 29-Nov 1)
- Sheraton Dallas Downtown
- Booth #TBD

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Appendix C

How FDA Regulates Animal Devices

Animal Health Literacy

CVM Kid's Page

The Federal Food, Drug, and Cosmetic Act (the Act) defines medical device as *"an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or [which is] intended to affect the structure or any function of the body of man or other animals ... ." Further, a device "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals, and ... is not dependent upon being metabolized for the achievement of its primary intended purposes."* Examples of devices include such things as needles, syringes, surgical instruments, prosthetic devices, X-ray equipment, certain diagnostic test kits, and dental appliances.

FDA does have regulatory oversight over devices intended for animal use and can take appropriate regulatory action if an animal device is misbranded or adulterated.

Pre-market Approval is Not Required: The FDA **does not require** submission of a 510(k), PMA, or any pre-market approval for devices intended for animal use.

Device manufacturers who exclusively manufacture or distribute animal devices are not required to register their establishments or list animal devices with FDA and are exempt from post-marketing reporting. It is the responsibility of the manufacturer and/or distributor of these articles to assure that these animal devices are safe, effective, and properly labeled.

The FDA encourages veterinarians and animal owners to report adverse drug experiences and product defects associated with animal devices to FDA using Form FDA 1932a.

An animal device that is also a radiation emitting electronic product, such as an MRI device intended for animal use, must comply with all requirements for animal devices in addition to applicable requirements for radiation-emitting electronic products in 21 CFR 1000 - 1050. FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating radiation-emitting electronic products. For further information on CDRH regulations that apply to manufacturers of electronic products, visit FDA's website on Radiation Emitting Products.

Manufacturers and/or distributors of animal medical devices may request a review of their product labeling and promotional literature to ensure that it complies with the Act by emailing AskCVM@fda.hhs.gov. This includes devices marketed in another country and offered for importation into the U.S.

Additional Information

- Reporting Problems with Animal Devices
- CPG Sec. 607.100 - Adequate Directions for Use (Species Designation) - Animal Drugs and Veterinary Devices
- About the Center for Devices and Radiological Health
- CDRH Medical Device Cybersecurity Resources

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