December 5, 2019

MCI Medical Concept Innovation Inc.
% Janine Treter
Regulatory Affairs Specialist
Passarini Regulatory Affairs of America LLC
201 Biscayne Blvd, Suite 1200
Miami, Florida 33131

Re: K182758
Trade/Device Name: MCI - CMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: November 4, 2019
Received: November 6, 2019

Dear Janine Treter:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182758

Device Name

MCI - CMF System

Indications for Use *(Describe)*
MCI - CMF System is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.

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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510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name	MCI Medical Concept Innovation Inc. 4592 North Hiatus Road Sunrise, Florida, USA 33351
Official Contact	Carlos Lacerda, Mr. Manager Director MCI Medical Concept Innovation Inc. E-Mail: carlos.lacerda@mci-medical.com Telephone +01 (954) 306-2521
Date Prepared	05/Dec/2019
Preparer / Alternate Contact	Janine Treter Regulatory Affairs Specialist Passarini Regulatory Affairs janine@rapassarini.com.br

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	MCI - CMF System
Common Names	Bone Plate; Fixation Screws
Primary Classification Name	Bone Plate
Primary Classification Regulation	21 CFR 872.4760, Class II
Primary Product Code	JEY
Subsequent Classification Name	Intraosseous Fixation Screw or Wire
Subsequent Classification Regulation	21 CFR 872.4880, Class II
Subsequent Product Code	DZL
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate Device	**K180204** - CranioMaxillofacial Fixation (CMF) System - CMF Visionare - Visionare LLC
Reference Devices	**K944565** -KLS-MARTIN MICRO OSTEOSYTHESIS SYSTEM(1.5MM) - KLS-MARTIN L.P. **K943347** - KLS Mini Osteosynthesis System - KLS-MARTIN L.P. **K083388** - Synthes MatrixORTHOGNATHIC Plate System - Synthes (USA) **K091233** - SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES - SYNTHES (USA)

K022185 - Universal CMF System - Stryker Leibinger
K182609 - Delphos Implants Rigid Fixation System - Delphos Implants - Ind. Com. Importação e Exportação
K140037 & **K160363** - Optimus CMF System - Osteonic Co., Ltd.
K050934 - MODUS® Titanium Osteosynthesis System - Medartis Inc.
K091679 & **K103778** - LeForte Neuro System Bone Plate - Jeil Medical Corporation

INDICATIONS FOR USE

MCI - CMF System is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.

SUBJECT DEVICE DESCRIPTION

The bone plates are made from commercially pure titanium (ASTM F67) and the bone screws are manufactured from titanium alloy - Ti-6Al-4V (ASTM F136) and are available in different sizes and shapes, according the site of the implantation and the extension of the fracture. The surface of plates and screws are colored-anodized.

MCI - CMF System implant devices are for single use. The devices are provided non-sterile and must be properly cleaned, disinfected and sterilized before use, according the recommendations provided in the Instructions for Use.

The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in maxillofacial surgery.

TECHNOLOGICAL CHARACTERISTICS COMPARISON TABLE

The subject and the predicate devices have a range of plates and screws with the same indication for reconstructive surgery, for fixation of maxillofacial and oral fractures, orthognathic reconstructions, mandibular reconstruction and any osteotomy surgery or trauma in maxillofacial.

The subject device is substantially equivalent to the primary predicate device K180204 in intended use, Indications for Use, designs, materials, and function.

The indication for use statement of the subject devices, primary predicate and reference devices is shown in **Table 5.1**. The indication for use statement of subject and primary predicate device is identical. A comparison between the design and features of the subject devices, primary predicate and reference devices is shown in tabular format for plates (**Tables 5.2 and 5.3**) and screws (**Table 5.4**).

The subject device plates are substantially equivalent to the primary predicate device K180204, or reference devices K944565, K943347, K083388, K091233, K022185, K182609, K140037 & K160363, K050934, K091679 & K103778, in designs and range of dimensions. Differences in the plates design features and dimensions between the subject device and the primary predicate device K180204 are addressed by comparison to the reference devices.

For System 1.5, the reference device K944565 is for substantial equivalence of part of the Straight Micro Plates, Straight Micro Plates Bridge, L Micro Plates Bridge, and Y Micro Plates Bridge. It is for substantial equivalence of the Orbital Micro Plates, Micro Plate L Oblique Bridge, H Nasal Micro Plate, I Nasal Micro Plate, Orbital Floor Micro Mesh and 3D Micro Mesh of 83x83, 122x 122 and 200x200 mm. For System 2.0, the reference device K944565 is for substantial equivalence of part of the Mini Plate Double Pillar for Ment.

The reference device K943347 for System 1.5 is for substantial equivalence of T Micro Plate Bridge 4 holes in design only. For System 2.0, the reference device K943347 is for substantial equivalence of L Mini Plates and L Mini Plates Bridge of 6 holes. Both are reversible plates and are covered by two plates of the reference device in the same design (right/left). It is also for substantial equivalence of T Mini Plate Bridge of 4 holes, Straight Mini Plates Bridge Tab, Chin Mini Plates Tab, L Mini Plates Bridge Tab and L Mini Plates Bridge Double Tab.

The reference device K083388 for System 1.5 is for substantial equivalence of part of the Micro Plate Bridge. It is for the substantial equivalence of the Micro Plates L Orbital Oblique Bridge. For system 2.0, this reference device is for substantial equivalence of the Straight Mini Plate of 20 holes, L Mini Plate Oblique Bridge, Sagittal Mini Plates Cut Bridge and Sagittal Mini Plates Cut Oblong Bridge.

The reference device K091233 for System 2.0 is for substantial equivalence of Lambda Mini Plates, Support Mini Plates, Trapezoidal Mini Plates and Trapezoidal Parallel Mini Plates.

The reference device K022185 for System 1.5 is for substantial equivalence of part of the T Micro Plate Bridge of 5 holes. It is for substantial equivalence of the Orbital Floor Plate. For System 2.0, K022185 is for substantial equivalence of T Mini Plate of 6 holes, T Orbital Mini Plate Bridge, and for the design features not emcopassed by K944595 for the Mini Plate Double Pillar for Ment.

The reference device K182609 for System 1.5 is for substantial equivalence of the Straight Micro Plate design features not encompassed by K944565, part of the 4 and 6 holes Straight Micro Plates Bridge and for the design features of the T Micro Plates Bridge 5 holes not completely emcopassed by K022185. The K182609 is also for the substantial equivalence of X Micro Plate Bridge and Support Zygomatic Micro Plates. For System 2.0, the reference device K182609 is for substantial equivalence of the Straight Mini Plate of 6 holes, Straight Mini Plate Bridge of 4 holes and for part of the Straight Mini Plate Bridge of 6 holes. It is for the substantial equivalence of the Orbital Mini Plates of 8 and 10 holes, Y Mini Plate, Mini Plates Double Line Bridge and for substantial equivalence of the Chin Mini Plates not encompassed by the primary predicate device.

The reference devices K140037 & K160363 for System 1.5 are for substantial equivalence of the Lefort Micro Plates. For System 2.0 are for substantial equivalence of Straight Mini Plates not emcopassed by K083388 and K182609 and for the Orbital Mini Plate not emcopassed by K182609. The reference devices K140037 & K160363 are also for the substantial equivalence of BSSO Dual Angled Mini Plates Bridge.

For System 1.5 the reference device K050934 is for substantial equivalence of the Straight Micro Plate Bridge features not emcopassed by K944565 and K182609, and of the L Micro Plates Bridge features not encompassed by K944565 and K083388. It is also for substantial equivalence of Y Micro Plate Bridge not emcompassed by K944565 and 3D Micro Mesh of 50x50 mm. For System 2.0 is for substantial equivalence of Straight Mini Plates Bridge not emcopassed by K182609 and L Mini Plates

Bridge not encompassed by K943347. It is also for the substantial equivalence of the Mini Plate Sagittal.

The reference devices K091679 & K103778 for System 1.5 are for substantial equivalence of Angled Micro Plates for Piriformis.

The subject device screws are substantially equivalent to the primary predicate device K180204, or reference devices K944565 and K022185, in designs and range of dimensions for all types of screws: Cortical Screw, Emergency Cortical Screw, Cortical Screw AP and Locking Screw AP. Differences in the screw design features and dimensions between the subject device and the primary predicate device K180204 are addressed by comparison to the reference devices.

For screws, the reference device K944565 is for substantial equivalence on the results of comparative performance testing. The reference device K022185 is for substantial equivalence of the length 20 mm for Cortical Screws of 2.0 mm diameter and Emergency Cortical Screw of 2.3 mm. The reference device K022185 is also for substantial equivalence of the Cortical Screws AP of 2.0 mm in diameter for the length of 4 mm.

Table 5.1: Comparison on indication for use statement

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT	SUBSTANTIAL EQUIVALENCE DISCUSSION
SUBJECT DEVICE	**K182758** – MCI - CMF System MCI Medical Concept Innovation Inc.	MCI - CMF System is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.	**Equivalent** The indication for use of subject and primary predicate device is identical. The subject device indication for use is within the scope of indications of the reference devices. Despite of the reference devices "K091679 & K103778 - LeForte Neuro System Bone Plate" citing the word Neuro in their proprietary name, by the indication for use itself is possible to understand they remain in the scope since are related to midface and craniomaxillofacial applications. Therefore, K091679 & K103778 are suitable as reference predicates.
PRIMARY PREDICATE DEVICE	**K180204** - CranioMaxillofacial Fixation (CMF) System - CMF Visionare Visionare LLC	CranioMaxillofacial Fixation (CMF) System - CMF Visionare is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.	
REFERENCE DEVICES	**K944565** -KLS-MARTIN MICRO OSTEOSYTHESIS SYSTEM(1.5MM) KLS Martin LP	*No 510(k) summary available*	
	K943347 - KLS Mini Osteosynthesis System KLS-MARTIN L.P.	*No 510(k) summary available*	
	K083388- Synthes MatrixORTHOGNATHIC Plating System	The Synthes MatrixORTHOGNATHIC Plating System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery;	

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT	SUBSTANTIAL EQUIVALENCE DISCUSSION
	Synthes (USA)	reconstructive procedures; and selective orthognathic surgery of the maxilla, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific Indications for Use: • Fractures ofthe midface and craniofacial skeleton • LeFort I osteotomies, sagittal split osteotomies and genioplasties • Orthognathic surgery including reconstructive procedures	
	K091233 - SYNTHES MATRIXMANDIBLE SUBCONDYLAR PLATES SYNTHES (USA)	The Synthes MatrixMANDhIBLE Subcondylar Plates are intended for oral, maxillofacial surgery; trauma and reconstructive surgery, specifically for fractures of the subcondylar region of the mandible and fractures of the condylar basis region of the mandible.	
	K022185 - Universal CMF System Stryker Leibinger	The Stryker® Leibinger Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction.	
REFERENCE DEVICES	**K182609 -** Delphos Implants Rigid Fixation System Delphos Implants - Ind. Com. Importação e Exportação	The Delpos Implants Rigid Fixation System is intended for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognatic reconstruction.	

	KNUMBER/ MANUFACTURER	INDICATION FOR USE STATEMENT	SUBSTANTIAL EQUIVALENCE DISCUSSION
		The Delpos Implants Rigid Fixation System implants are intended for single use only.	
	K140037 & **K160363** - Optimus CMF System Osteonic Co., Ltd.	Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed.	
	K050934 - MODUS® Titanium Osteosynthesis System Medartis, Inc.	The MODUS® Titanium Osteosynthesis System is intended for osteotomies and fractures involving any part ofthe craniofacial skeleton and requiring positional and functional stability. Indications include fixation in the nasoethmoidal, intraorbital, and frontal sinus areas; fixation of comminuted fractures of maxillo-facial and craniofacial areas; tumor surgery for defect bridging; reconstruction of bony structures by means of mesh materials; coverings for burr holes in the skull; trauma of nasal bones; surgical correction of dento facial deformations; and reconstruction after tumor surgery.	
	K091679 & **K103778 -** LeForte Neuro System Bone Plate Jeil Medical Corporation	This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognatic surgery of the maxilla and chin.	

Table 5.2: Comparison between the subject, primary and reference K944565, K943347, K083388, K091233 devices for plates *(to be continued)*

COMPARISON	SUBJECT DEVICE			PRIMARY PREDICATE DEVICE			REFERENCE DEVICES											
	K182758			K180204			K944565			K943347			K083388			K091233		
Product Code	JEY, DZL			JEY, DZL			JEY			JEY			JEY, DZL			JEY		
Raw Material	CP Titanium			CP Titanium			CP Titanium			CP Titanium			CP Titanium			CP Titanium		
Surface treatment	Anodized			Anodized			Anodized			Anodized			Anodized			Anodized		
	System 1.5																	
Design/Features	**Description**	**Hole n°**	**Thickness (mm)**	**Description**	**Hole n°**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**
	Straight Micro Plate			**Straight Mini Plate Regular**			**Micro Plate**			**Mini Plate**								
		4, 6, 8, 10, 16, 20	0.6		4, 6, 8, 16, 20	0.7		4, 6, 8, 16, 20	0.6		4, 6, 8, 16	0.6, 1.0						
	Straight Micro Plate Bridge			**Straight Mini Plate Medium**			**Micro Plate**											
		4, 6	0.6		4, 6	0.7		4, 6	0.6									
	Orbital Micro Plate			**Orbital Mini Plate Regular**			**Micro Plate**			**Champy Plate**								
		8, 10	0.6		8, 10	0.7		8, 10	0.6		8, 10	0.6						
	L Micro Plate Bridge			**L Mini Plate Medium & Extra Long**			**Micro Plate**			**Mini Plate**			**90° L Plate Medium & Long**					
		4	0.6		4	0.7		4	0.6		4	0.6, 1.0		4	0.5			
	L Micro Plate Oblique Bridge						**Micro Plate**											
		4, 5	0.6					4, 5	0.6									
	L Micro Plate Orbital												**Anatomical L Plate**					
		6	0.6, 0.7, 0.8											6	0.5, 0.7, 0.8			
	T Micro Plate Bridge			**T Mini Plate Medium & Extra Long**						**Champy Plate**								
		4, 5	0.6		5	0.7					4	1.0						
	X Micro Plate Bridge			**T Mini Plate Medium & Extra Long**			**Micro Plate**											
		6	0.6		6	0.7		6	0.6									
	Y Micro Plate Bridge						**Micro Plate**											
		5	0.6					5	0.6									
	Lefort Micro Plate						**Lindorf Micro Le Fort I Plate**											
		11	0.6					11	1.0									
	Angled Micro Plate Piriforms			**Le Fort Mini Plate**														
		10	0.8		14	0.8												
	Support Zygomatic Micro Plate																	
		7	0.8															
	H Nasal Micro Plate						**Micro Plate**			**Mini Plate**								
		12	0.6					12	0.6		12	0.6						
	I Nasal Micro Plate						**Micro Plate**											
		11, 12	0.6					11, 12	0.6									

K182758 – MCI -CMF System

COMPARISON	SUBJECT DEVICE			PRIMARY PREDICATE DEVICE			REFERENCE DEVICES											
	K182758			K180204			K944565			K943347			K083388			K091233		
Design/Features	**Orbital Floor Micro Mesh**						**Micro Orbital Mesh**											
	---	0.3, 0.5						---	0.3, 0.5									
	Orbital Floor Plate																	
	---	0.3																
	3D Micro Mesh						**3D-Mesh**											
	50x50 83x83 122x122 200x200	0.6						80x80 120x120 200x200	0.6									
	System 2.0																	
Design/Features	**Description**	**Hole n°**	**Thickness (mm)**	**Description**	**Hole n°**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**	**Description**	**Holes**	**Thickness (mm)**
	Straight Mini Plate			**Straight Mini Plate Regular**									**Adaptation Plate**					
	4, 6, 12, 16, 20	0.9		4, 6, 12, 16, 20	1.0									20	0.8			
	Straight Mini Plate Bridge			**Straight Mini Plate Bridge**						**Mini Plate Bridge**								
	4, 6	0.9			4, 6	1.0					4	1.0						
	Orbital Mini Plate			**Orbital Mini Plate**						**Champy Plate Bridge**								
	6, 8, 10	0.9			6, 8, 10	1.0					8, 10	0.6						
	L Mini Plate			**L Mini Plate Regular**						**Mini Plate**								
	4, 6	1.0			4	1.0					4, 5	1.0						
	L Mini Plate Bridge			**L Mini Plate Long**						**Mini Plate**								
	4, 6	1.0			4	1.0					6	1.0						
	L Mini Plate Oblique Bridge												**Oblique L Plate**					
	6	1.0												6	0.8			
	T Mini Plate									**Mini Plate**								
	4	1.0									4, 6	1.0						
	6	0.9																
	T Orbital Mini Plate																	
	8	0.9																
	Y Mini Plate																	
	5	0.9																
	S/Z Mini Plate			**Z Mini Plate**						**Mini Plate**								
	4	1.0			4	1.0					4	0.6						
	BSSO Dual Angled Mini Plate Bridge						**BSSO Dual Angled Mini Plate Bridge**											
	8	0.9, 1.0						8	0.9, 1.0									
	Straight Mini Plate Bridge Tab									**Mini Plate Mandibular Tab**								
	4, 6	1.0									4	1.0						
	Chin Mini Plate			**Chin Mini Plate**														
	4	0.9			4	0.7												
Design/Features	**Chin Mini Plate Tab**									**Mini Plate Mandibular Tab**								
	4	0.8									4	0.8						

K182758 – MCI -CMF System

COMPARISON	SUBJECT DEVICE			PRIMARY PREDICATE DEVICE			REFERENCE DEVICES											
	K182758			K180204			K944565			K943347			K083388			K091233		
	L Mini Plate Bridge Tab									Arnett Orthognathic System Maxilla								
		4	0.9								4	0.8						
	L Mini Plate Bridge Double Tab									Arnett Orthognathic System Maxilla								
		4	0.9								4	0.8						
	Sagittal Mini Plate Cut Bridge												Sagittal Split Plate Bar					
		6	1.0											6	1.0			
	Sagittal Mini Plate Cut Oblong Bridge												Sagittal Split Plate Oblong Bar					
		4	1.0											4	1.0			
	Mini Plate Sagittal																	
		4	1.0															
	Lambda Mini Plate															Subcondylar Lamda Plate		
		7	1.0														7	1.0
	Support Mini Plate															Subcondylar Strut Plate		
		5	1.0														5	1.0
	Trapezoidal Mini Plate															Subcondylar Trapezoidal Plate		
		4	1.0														4	1.0
	Mini Plate Double Pillar for Ment						Micro Plate											
		6	0.6					6	0.6									
Sterilization	Non-sterile, Steam sterilized prior to use			Non-sterile, Steam sterilized prior to use														
Single Use	Yes			Yes			Yes			Yes			Yes			Yes		

Table 5.3: Comparison between the subject and reference devices K022185, K182609, K140037 & K160363, K050934, K091679 & K103778 for plates

COMPARISON	SUBJECT DEVICE			REFERENCE DEVICES														
	K182758			K022185			K182609			K140037 & K160363			K050934			K091679 & K103778		
Product Code	JEY, DZL			JEY, HWC			JEY			JEY, DZL			JEY			JEY		
Raw Material	CP Titanium			Not informed			CP Titanium			CP Titanium			CP Titanium			CP Titanium		
Surface treatment	Anodized			Anodized			Anodized			Anodized			Anodized			Anodized		
	System 1.5																	
Design/Features	Description	Hole n°	Thickness (mm)	Description	Hole n°	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)
	Straight Micro Plate			Standard Plate 1.2 Upper Face			Regular Straight Plate			Mini Plate			Cranial Plate Straight			Straight Mid Plate		
		4, 6, 8, 10, 16, 20	0.6		8, 24	0.6		10	0.6		4, 8, 12, 20	0.5		4, 16	0.5		4, 6, 10	0.6
														6, 8	0.6			
	Straight Micro Plate Bridge						Straight Plate Bridge						Cranial Plate Straight Bar			Straight Mid Plate Long		
		4, 6	0.6					4, 6	0.6					4, 6	0.6		4	0.6
	Orbital Micro Plate			Curved Plate									Orbital Plate Curved			Orbital Mid Plate		
		8, 10	0.6		10	0.6								8	0.6		8, 10	0.6
	L Micro Plate Bridge						L Plate Bridge			Mini Plate			Cranial Plate L Bar			L Mid Plate 90°		
		4	0.6					4	0.6		4	0.5		4	0.6		4	0.6
	L Micro Plate Oblique Bridge												Cranial Plate L 100°			L Mid Plate 100°		
		4, 5	0.6											4, 5	0.6		4	0.6
	L Micro Plate Orbital									Anatomical Plate								
		6	0.6, 0.7, 0.8								6	0.8						
	T Micro Plate Bridge			T-Plate			T-Plate									T Micro Plate		
		4, 5	0.6		5	0.6		5	0.6								5	0.5
	X Micro Plate Bridge						X-Plate Bridge			Mini Plate			Cranial Plate X Bar			Double Y Mid Plate		
		6	0.6					6	0.6		6	0.5		6	0.6		6	0.6
	Y Micro Plate Bridge						Y-Plate Bridge						Cranial Plate Y Bar					
		5	0.6					5	0.6					5	0.6			
	Lefort Micro Plate			Le Fort I Plate						Le Fort I Plate								
		11	0.6		11	0.9					11	0.6, 1.0						
	Angled Micro Plate Piriforms						Bifurcated Anterior Maxillary Plate			Segmental Le Fort I Plate						RC Micro Plate		
		10	0.8					12	0.8		12	1.0					12	0.8
	Support Zygomatic Micro Plate						Pre-shaped Posterior Maxillary Plate											
		7	0.8					7	0.8									
	H Nasal Micro Plate												Nasal Plate H Bar			H Micro Plate		
		12	0.6											12	0.6		12	0.5
	I Nasal Micro Plate												Cranial Plate H Bar					
		11, 12												11	0.6			
	Orbital Floor Micro Mesh			Orbital Floor Plate												Orbital Floor Mid Plate		
		---	0.3, 0.5		---	0.3, 0.4											---	0.3
	Orbital Floor Plate			Orbital Floor Plate									Orbital Floor Plate			Orbital Floor Mid Plate		
		---	0.3		---	0.3								---	0.3		---	0.3

K182758 – MCI -CMF System

COMPARISON	SUBJECT DEVICE			REFERENCE DEVICES														
	K182758			K022185			K182609			K140037 & K160363			K050934			K091679 & K103778		
Design/Features	3D Micro Mesh			3D Standard Plate						Hexagonal Mesh			Vario Mesh			Mesh Mid Plate		
		Dimension: 50x50 mm 83x83 mm 122x122 mm 200x200 mm	0.6		10x10 holes	0.6 mm					Dimension: 50x49	0.2		Dimension: 50x49	0.3		Dimension: 48x33.6	0.6
	System 2.0																	
Design/Features	Description	Hole n°	Thickness (mm)	Description	Hole n°	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)	Description	Holes	Thickness (mm)
	Straight Mini Plate			Straight Plate Regular			Straight Plate			Straight Plate			Cranial Plate Straight			Straight Mini Plate		
		4, 6, 12, 16, 20	0.9		4, 6	1.0		6	0.8		4, 6, 16, 20	0.8		4, 6, 20	0.7		6, 16	0.8
					16	0.8					12	0.7		16	1.0			
	Straight Mini Plate Bridge						Straight Plate Bridge			Straight Plate			Cranial Plate Straight Bar			Straight Mini Plate		
		4, 6	0.9					4, 6	0.8		4	0.8		4, 6	1.0		4	0.8
	Orbital Mini Plate			Curved Plate			Curved Plate			Mini Plate			Orbital Plate Curved			Orbital Mini Plate		
		6, 8, 10	0.9		12	0.8		8, 10	0.8		6, 8, 10	0.5		6, 8	1.0		10	0.8
	L Mini Plate			L-Plate												L Mini Plate 90° Regular		
		4, 6	1.0		4, 5	1.0											4	1.0
	L Mini Plate Bridge												Cranial Plate L 90° Bar			L Mini Plate 90° Long		
		4, 6	1.0											4	0.7		4	1.0
	L Mini Plate Oblique Bridge																	
		6	1.0															
	T Mini Plate			T-Plate														
		4	1.0		6	1.0												
		6	0.9															
	T Orbital Mini Plate			T-Plate														
		8	0.9		8	0.8												
	Y Mini Plate			Y-Plate			V-Plate						Cranial Plate L 90° Bar					
		5	0.9		5	1.0		5	0.8					5	1.0			
	S/Z Mini Plate			Z-Plate						Z-D Plate								
		4	1.0		4	0.8					4	0.8						
	BSSO Dual Angled Mini Plate Bridge			BSSO Plate Double			OSS Plate Double											
		8	0.9, 1.0		8	0.8		8	1.0									
	Straight Mini Plate Bridge Tab																	
		4, 6	1.0															
	Chin Mini Plate						Mentoplasty Plate			Chin X-Plate						Chin Mini Plate		
		4	0.9					4	0.7		4	1.0					4	0.6
	Chin Mini Plate Tab																	
		4	0.8															
	L Mini Plate Bridge Tab																	
		4	0.9															
Design/Features	L Mini Plate Bridge Double Tab																	
		4	0.9															

K182758 – MCI -CMF System

COMPARISON	SUBJECT DEVICE			REFERENCE DEVICES															
	K182758			K022185			K182609			K140037 & K160363			K050934			K091679 & K103778		
	Sagittal Mini Plate Cut Bridge																		
		6	1.0																
	Sagittal Mini Plate Cut Oblong Bridge																		
		4	1.0																
	Mini Plate Sagittal												Sagittal Split Plate Closed						
		4	1.0											6	1.0				
	Lambda Mini Plate																		
		7	1.0																
	Support Mini Plate																		
		5	1.0																
	Trapezoidal Mini Plate												T.C.P. Trapezoid Condyle Plate			Condyle Plate		
		4	1.0											4	1.0		4	1.0
	Mini Plate Double Pillar for Ment			Chin Plate Bar															
		6	0.6		6	0.6													
Sterilization	Non-sterile, Steam sterilized prior to use			Non-sterile, Steam sterilized prior to use															
Single Use	Yes			Yes			Yes			Yes			Yes			Yes			

Table 5.4: Comparison between the subject, primary and reference predicate devices for screws

COMPARISON	SUBJECT DEVICE			PRIMARY PREDICATE DEVICE			REFERENCE DEVICES					
	K182758			K180204			K944565			K022185		
Product Code	JEY, DZL			JEY, DZL			JEY			JEY, HWC		
Raw Material	Titanium alloy (Ti-6Al-4V)			Titanium alloy (Ti-6Al-4V)			Titanium alloy (Ti-6Al-4V)			Not informed		
Surface treatment	Anodized			Anodized			Anodized			Anodized		
	Systems 1.5 and 2.0											
Design/Features	**Type**	**Diameter**	**Length**	**Type**	**Diameter**	**Length**	**Type**	**Diameter**	**Length**	**Type**	**Diameter**	**Length**
System 2.0	**Cortical Screw** (Self-tapping)			**Self-tapping Screw**			**Self-retaining Screw maxDrive**			**Self-tapping Screw**		
		1.5	4, 5, 6, 8, 9, 10, 11, 12, 14, 15		1.5	4, 5, 6, 8, 9, 10 11, 12, 14, 15		1.5	4, 5, 6, 8, 9, 11, 15			
		2.0	4, 5, 6, 8, 10, 12, 14, 16, 18, 20		2.0	4, 5, 6, 8, 10, 12, 14, 16, 18					2.0	4, 5, 6, 8, 10, 12, 14, 16, 18, 20
	Cortical Screws (Emergency Self-tapping)			**Emergency Self-tapping Screw**						**Self-tapping Screw**		
		1.7	5, 6, 8, 10, 12								1.7	5, 6, 8, 10, 12
		2.3	5, 6, 8, 10, 12, 14, 16, 18, 20		2.3	5, 6, 8, 10, 12, 14, 16, 18					2.3	5, 6, 8, 10, 12, 14, 16, 18, 20
	Cortical Screw AP (Self-drilling)			**Self-drilling Screw**			**Drill-Free Screw maxDrive**			**MP Self-drilling**		
		1.5	4, 5, 6, 7		1.5	4, 5, 6, 7		1.5	4, 5, 6, 7			
		2.0	4, 5, 6		2.0	5, 6					2.0	4, 5, 6
	Locking Screw AP (Self-drilling Blocking Screw)			**Blocking Screw**								
		2.0	6, 8, 10, 12		2.0	6, 8, 10, 12						
Sterilization	Non-sterile, Steam sterilized prior to use			Non-sterile, Steam sterilized prior to use			Non-sterile, Steam sterilized prior to use			Non-sterile, Steam sterilized prior to use		
Single Use	Yes			Yes			Yes			Yes		

PERFORMANCE DATA

The following performance data supports the substantial equivalence determination:

Biocompatibility testing

The plates are manufactured in commercially pure titanium conforming to ASTM F67 and its surfaces are colored-anodized. The plates types of titanium are the same to that used for fabrication of the primary predicate and reference devices.

The screws are made of titanium alloy conforming to ASTM F136 and its surfaces are colored-anodized. The screws alloy is the same to that used for fabrication of the primary predicate and reference devices.

Biocompatibility of the subject devices were supported by the following tests according to its contact profile: Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Intracutaneous Reactivity (ISO 10993-10), Acute Systemic Toxicity (ISO 10993-11), Subchronic Systemic Toxicity (ISO 10993-11), Implantation (ISO 10993-6), Genotoxicity and Carcinogenicity (ISO 10993-3).

Mechanical testing

The performance of the subject devices are demonstrated through mechanical testing of plates and screws according to ASTM F382 and ASTM F543.

For the plates the 4 point bending fatigue test was performed. For the screws, pullout, torsion, and driving torque were executed. No clinical data were included in this submission.

Shelf life and Sterilization testing

The subject devices are provided non-sterile and have no expiration date defined. Steam sterilization validation was performed according to ISO 17665-1 and 17665-2.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified primary predicate and reference devices.