DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 26, 2016

Eli-Ka Technologies
Mr. Luigi Girotto
209 Madison Ave.-Suite D
Monrovia, CA 91016

Re: K151540
Trade/Device Name: MC BIO "SuperTack " tack 3mm, 4mm and 5mm
Regulation Number: 21 CFR 872.4880
Regulation Name: Intra-osseous fixation screw or wire
Regulatory Class: II
Product Code: DZL
Dated: May 28, 2015
Received: April 27, 2016

Dear Mr. Girotto:

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. 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); 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151540

Device Name
MC BIO Supertack tack 3mm, 4mm and 5mm

Indications for Use *(Describe)*

The MC Bio Supertack tacks are used for the stabilization of absorbable and non-absorbable membranes during the bone tissue regeneration and bone repair in the maxillofacial or mandibular area.

The MC Bio Supertack system is designed to stabilize barrier membranes onto cortical plate bone, this may be used in maxillofacial or mandibular bone.

General patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.

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.

EliKa Technologies 209 Madison Ave. - Suite D Monrovia, CA 91016	**MC Bio Supertack**	**Annex 1 R.4** ***May 25, 2016***

510(k) Summary

510 (k) OWNER: Eli-Ka Technologies, 209 Madison Ave. - Suite D, Monrovia, CA 91016 - USA Tel: 626-256-3674
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MANUFACTURER NAME: MC Bio s.r.l., Via Cavour 2, 22074 LOMAZZO (CO) - ITALY
Tel.: +39 02 36714256 - +39 02 36714257 - Fax: +39 02 36714261 - Email: administration@coneimplant.com

Trade Name: MC BIO "SuperTack" tack 3mm, 4mm and 5mm

Common Name: Tack, Pin, Membrane fixation system

Classification Name: Intra-osseous fixation screw or wire

Product Code: DZL

Classification Regulation: 21 CFR 872.4880

Class: II

PREDICATE DEVICE (PRIMARY): K100182 - SALVIN Bone Tack 3mm and 5mm

REFERENCE PREDICATE DEVICE :

Company	Trade Name	510 (k) Summary
Biohorizons Implant Systems, Inc.	The AutoTac SystemTM Titanium Tack	KO22790
Hager & Meisinger GmbH	Meisinger MEITAC	K130682
IMTEC Corporation	IMTEC Bone Tack	K973180
Porex Surgical, Inc	Medpore Fixation System- cranial	K101835
Lancer Orthodontics	Storm Mini Screw	K122069

DEVICE DESCRIPTION: The MC Bio SUPERTACK System consists of 3mm, 4mm and 5mm bone tacks and associated instrumentation.
The tacks material consist of Titanium alloy, as specified in ASTM F136 STANDARD for Wrought Titanium- 6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy, anodized blue color.
The devices are provided non-sterile.

INTENDED USE: The MC Bio Supertack tacks are used for the stabilization of absorbable and non-absorbable membranes during the bone tissue regeneration and bone repair in the maxillofacial or mandibular area.
The MC Bio SUPERTACK system is designed to stabilize barrier membranes onto cortical plate bone, this may be used in maxillofacial or mandibular bone.
Gnereral patient health, bone type and quality, and functional loads exerted should be considered and carefully evaluated prior to use.

TECHNOLOGICAL FEATURES: as described in this submission the MC Bio SUPERTACK is substantially equivalent to the predicate or to other devices cleared by the agency for commercial distribution in the United States. The analysis of the mechanical properties, the indication for use, the materials, the labelling etc., between the predicate and the subject device, have demonstrated that the MC Bio SUPERTACK is substantially equivalent to the predicate.

Device	**Salvin Bone Tack System**	**MC Bio Supertack System**
TECHNICAL DRAWING FEATURES **3mm TACK**	1-Lenticular Head . 2-Tapered Head 3-No thread on the shaft 4-Barb at the tip	1-Lenticular Head . 2-Tapered Head 3-No thread on the shaft 4-Barb at the tip
TECHNICAL DRAWING FEATURES **5mm TACK**	1-Lenticular Head . 2-Tapered Head 3-No thread on the shaft 4-Barb at the tip	1-Lenticular Head . 2-Tapered Head 3-No thread on the shaft 4-Barb at the tip
Use	To stabilize Barrier Membranes onto cortical bone plates	To stabilize Barrier Membranes onto cortical bone plates
Tack MATERIAL	Ti 6Al 4V	Ti 6Al 4V
Tack NOMINAL LENGTH	3mm – 5mm	3mm – 4mm – 5mm
Tack HEAD DIAMETER	2.475 mm	2.50 mm
Sterility condition (out of the firm) of the tacks	NON-STERILE	NON-STERILE
Recommended Sterilization method	Steam	Steam

Way to take the tack from the tack holder and to carry it to the placement site	Pressing the Insertion Instrument on the Head of the tack	Pressing the Insertion Instrument on the Head of the tack
Placement of the tack in the cortical bone	By a firm tap with the hammer on the Insertion instrument	By a firm tap with the hammer on the Insertion instrument
Stabilization of the tack in the Bone	The tack has a barb at the tip	The tack has a barb at the tip
Removing from the bone	The head tack has two tapered external areas, that allow to dislodge the tack by using a periosteal elevator, scalpel or other thin flat instrument	The head tack has two tapered external areas, that allow to dislodge the tack by using a periosteal elevator, scalpel or other thin flat instrument
Re-use of the tack	Not RECOMMENDED	MC Bio Supertacks are for single use only therefore reuse of the tacks is NOT recommended
Maximum duration of implantation	Time not defined	MC Bio Supertack tacks are not intended for long-term implantation, but should be removed upon completion of the healing process

NON-CLINICAL TESTING:

Test	Result
MTT cytotoxicity	No Cytoxic Potential
Sterilization validation	Steam Sterilization cycle validated
Flexional test	Reduction of max stress value vs. predicate

As described in the submission, engineering inspections, dimensional and technological comparisons and the MTT cytotoxicity test have demonstrated the equivalence with the predicate.
The Blue color of the MC Bio Supertack , obtained by anodization of the titanium, does not modify the biocompatibility of the material: Titanium alloy as specified in the ASTM F136 standard.

CONCLUSION: the function and intended use, material, possible product have been evaluated as acceptable and equivalent to predicated device

Based on the information provided in the summary, we conclude that the MC Bio Supertack tacks are equivalent to the legally marketed predicate device described.