DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 16, 2014

T.A.G. Medical Products Corporation, Limited
% George J. Hattub, RAC, CQE
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K142653
Trade/Device Name: G-Lok® and G-Lok® XL Extender
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 11, 2014
Received: September 18, 2014

Dear Mr Hattub:

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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142653

Device Name: The G-Lok® and G-Lok® XL Extender

Indications For Use: The G-Lok® and G-Lok® XL Extender are intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or assist in reconstruction surgeries and to assist in the management of reconstructive surgeries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special 510(k) Summary of Safety & Effectiveness

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	T.A.G. Medical Products Corporation, Ltd. D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: 972-4-985-8400
	Contact Person:	Erez Adiv RA/QA Director
	Date:	October 12, 2014
2.	***Device & Classification Name:***	Smooth or threaded metallic bone fixation fastener, class II device (product code MBI). G-Lok® and G-Lok® XL Extender
3.	***Predicate Devices:***	K101616- *GrappLR*™ and *GrappLR*™ *Extender*
4.	***Description:***	The G-Lok® suspension fixation device is a single-use, titanium implant used for fixation of soft tissue to bone. The G-Lok® has two configurations: One has a Continuous Loop, made of ultra high molecular weight polyethylene, offered in several sizes to accommodate various bone tunnel lengths. The second configuration does not have a loop, and enables custom loop lengths to be tied using an appropriate material (not included). Both of these configurations have a Lead Suture and an optional Flipping Suture. The G-Lok® XL Extender is a single-use, titanium implant used for providing additional button width and length to the G-Lok®.
5.	***Intended Use:***	The G-Lok® and G-Lok® XL Extender are intended to provide suspension fixation for soft tissue to bone in the repair of the natural ligament or tendon disruption or assist in reconstruction surgeries and to assist in the management of reconstructive surgeries.
6.	***Comparison of Technological Characteristics:***	With respect to its indication for use, the G-Lok® and G-Lok® XL Extender is substantially equivalent to its predicate devices in that it intended for the same clinical purpose. The purpose of this 510(k) was to add an optional Flipping Suture. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products Corporation, Ltd. believes that its device is safe and effective because it performs the same function in the same manner. The following table depicts the similarities and differences between the predicate device and the submitted device. In addition, the performance testing indicated equivalency to the predicate device.

Feature and Characteristic	Modified Device The G-Lok Button and G-Lok XL Extender	Predicate Device The GrappLR and GrappLR Extender
Button Material	Same	Titanium
Button Length	Same	13 mm
Button Width	Same	3.81 mm
Button Thickness	Same	2.20 mm
Button Hole Diameter(s)	1.5 mm and 1.2 mm	1.5 mm
Optional Extender	yes	yes
Extender Material	Same	Titanium
Extender Length	19.8 mm	19 mm
Extender Width	Same	5.0 mm
Extender Thickness	Same	3.3 mm
Extender Hole Diameter(s)	1.5 mm and 1.5 mm	1.5 mm
Loop Size	Same	15-50 mm
Loop Material	Same	Braided Polyethylene
Capability to be used with No Loop	yes	yes
Suture(s)	Two Tevdek™ Polyester Sutures (for leading and flipping)	One Tevdek™ Polyester Suture (for leading)
Delivery Mechanism	Same	Passing Pin (not provided)
Deployment Mechanism	Flip with Push Rod and/or Flip Suture	Flip with Push Rod

Feature and Characteristic	Modified Device The G-Lok Button and G-Lok XL Extender	Predicate Device The GrappLR and GrappLR Extender
Surgical Preparation (Tunnel Drilling)	Same	Same
Graft Preparation	Same	Same
Graft Attachment (Proximal)	Same	Same
Provided Single Patient Use Sterile	yes	yes
510(k) Number	Pending	K101616