August 5, 2026

T.A.G. Medical Products Corporation, Ltd.
Shlomi Dines
VP QA and RA
Kibbutz Gaaton
Gaaton Northern, IL 2513000
Israel

Re: K253858
Trade/Device Name: GFS - Sterile Screws and Top Hat
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 7, 2026
Received: July 7, 2026

Dear Shlomi Dines:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253858

Please provide the device trade name(s).

GFS - Sterile Screws and Top Hat

Please provide your Indications for Use below.

The GFS Sterile Screws and Top Hat are intended to provide orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries for cortical bone in the shoulder.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

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

Date	August 5, 2026
Submitter Address	T.A.G. Medical Products Corporation, Ltd. Gaaton 2513000, ISRAEL www.tag-med.com
Mfg. Phone	Tel.: 972-4-9858400
Contact Person	Shlomi Dines
Trade Name	GFS Sterile Screws and Top Hat
Device	Smooth or threaded metallic bone fixation fastener
Classification	Class II
Product Code	HWC
Regulation Number	21 CFR 888.3040
Predicate Device	K110763 – Latarjet Cortical Screw Set
Reference Devices	K083096 – Latarjet Cortical Screw Set K091694 – Latarjet Cortical Screw Set K101616 – GrappLR™ and GrappLR™ Extender
Description:	The GFS Sterile Screws and Top Hat Set consist of implantable fixation screws which are used for fixation of bone grafts or bone fragments to cortical bone in the shoulder. The screws are offered in the following size ranges 20 mm -48 mm in length. There is also a threaded bushing, "Top Hat", included. The top hat is attached to the proximal end of the fixation screw. The purpose is to position the screw firmly and safely during the procedure. The top hat or bushing is provided in one size. The proposed screws are provided sterile single use.
Indications for Use:	The GFS Sterile Screws and Top Hat are intended to provide orthopedic surgeon a means of bone fixation and to assist in the management of fractures and reconstructive surgeries for cortical bone in the shoulder.
Performance Data	Dimensional analysis was compared between the subject and predicate devices. Due to differences in thread geometry, axial pullout force and insertion torque testing was completed in comparison to the predicate per ASTM F543. The performed testing demonstrates the proposed GFS Sterile Screws are substantially equivalent to the predicate Latarjet Cortical Screw Set, K110763.
Comparison of Technological Characteristics:	In comparison to the predicate device, K110763, Latarjet Cortical Screw Set devices, the subject GFS Sterile Screws and Top Hat are identical in materials, surgical technique, and methods of manufacturing as the predicate. The proposed device, GFS Sterile Screws includes a change in dimensions, sterilization modality, shelf life, and packaging configuration.

Conclusion	The subject GFS Sterile Screws and Top Hat are substantially equivalent to the predicate device which the design features and intended use are identical. Differences between the subject and predicate device do not result in new or different questions of safety or effectiveness.