DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 8, 2016

Stryker Corporation
Ms. Meriam Gabera
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

Re: K160978
Trade/Device Name: Lite Bio Delivery System
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: April 6, 2016
Received: April 7, 2016

Dear Ms. Gabera:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K160978

Device Name
LITe® BIO Delivery System

Indications for Use *(Describe)*
The LITe® BIO Delivery System is intended to deliver autograft, allograft, or synthetic bone grafting materials to all orthopedic surgical sites.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary as required by 21CFR§807.92(c): LITe® BIO Delivery System	
Submitter	Stryker Spine 2 Pearl Court Allendale, NJ 07401
Contact Person	Meriam Gabera, MS Senior Regulatory Affairs Specialist Phone: 201-749-8043 Fax: 201-831-3000 E-mail: meriam.gabera@stryker.com
Date Prepared	July 1, 2016
Trade Name	LITe® BIO Delivery System
Common Name	Syringe, piston
Proposed Class	Class II
Classification Name, Codification	Piston syringe, 21 CFR § 880.5860
Product Codes	FMF
Predicate Devices	**Primary Predicate:** • Arthrex Mixing and Delivery System - K121124 **Additional Predicates:** • Biomet Graft Delivery Syringes - K140710 • NovaBone MIS Cartridge Delivery System - K112773 **Reference Devices:** • Imbibe Bone Marrow Aspiration Syringe – K023074 • Aero-AL Lumbar Cage System – K133328 • Aero-C Cervical Cage System – K152532
Device Description	The LITe® BIO Delivery System is a manually operated hand-held device used to facilitate delivery of bone graft material to all orthopedic surgical sites. The LITe® BIO Delivery System consists of a delivery cannula, a delivery plunger, a delivery plunger tip, a loading syringe, and a delivery handle. The cannula is filled with the physician's choice of bone graft material and is then delivered to the intended surgical site.
Indications for Use	The LITe® BIO Delivery System is intended to deliver autograft, allograft, or synthetic bone graft materials to all orthopaedic surgical sites.
Summary of Technological Characteristics	The LITe® BIO Delivery System shares similar materials, design, and fundamental scientific technologies as the predicate devices. An assessment of the technological differences was completed and the following differences were identified: • The design of the primary predicate system allows for mixing/preparing the bone graft mixture within the device as opposed to using an external surgical dish for preparing the bone graft material. • The primary predicate is supplied as a sterile, single use device

	while the subject device is supplied with both sterile, single use devices and non-sterile, reusable instruments. The comparison of the LITe® BIO Delivery System against the primary predicate system demonstrated that the identified design differences do not impact the functionality or performance of the subject system, supporting the claim of substantial equivalence.
Summary of Performance Data	Testing was conducted to demonstrate performance as intended and included the following bench testing: •Functional testing (delivery of graft material through cannula) •Life cycle testing •Cantilever bending of cannula •Radial compression of cannula •Retention strength test of cannula •Connection strength test of cannula to loading funnel The testing verifies that the subject device is substantially equivalent to other currently marketed bone graft delivery systems and any technological differences do not raise any new issues regarding safety and effectiveness.
Conclusion	Based upon a comparison of intended use, technological characteristics, and device performance in the non-clinical testing listed above, the LITe® BIO Delivery System has demonstrated substantial equivalence to the identified predicate device systems.