June 23, 2023

Spineart
% Michael Coladonato
Senior Associate, Spine Regulatory Affairs
Mcra LLC
803 7th Street Northwest
Third Floor
Washington, District of Columbia 20001

Re: K230774
Trade/Device Name: PERLA® TL System; TEKTONA® HV US Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: PML, NKB, KWP
Dated: May 26, 2023
Received: May 26, 2023

Dear Michael Coladonato:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230774

Device Name
Perla® TL System

Indications for Use *(Describe)*
The PERLA® TL system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- degenerative disc disease;
- spondylolisthesis;
- fracture;
- dislocation;
- scoliosis;
- kyphosis;
- spinal tumor;
- and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When used in conjunction with TEKTONA® HV US bone cement system, the PERLA®TL system is intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time, in patients whom life expectancy is of insufficient duration to permit achievement of fusion in advanced stage of thoracic and lumbar spine tumors. The PERLA®TL 35mm to 60mm lengths Screws augmented used with TEKTONA® HV US bone cement system are intended to be used at spinal levels where the structural integrity is not severely compromised.

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230774

Device Name
TEKTONA® HV US Bone Cement

Indications for Use *(Describe)*
TEKTONA® HV US Bone Cement is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with PERLA®TL system, TEKTONA® HV US Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. PERLA®TL Screws augmented with TEKTONA® HV US Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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.

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

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510(k) Summary

Device Trade Name:	PERLA® TL System TEKTONA® HV US Bone Cement
Manufacturer:	Spineart 3 Chemin de Pré Fleuri 1228 Plan Les Ouates Geneva, Switzerland +41 22 570 1200
Contact:	Franck Pennesi Chief Technical Officer +41 22 570 1200 fpennesi@spineart.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	March 20, 2023
Classifications:	21 CFR 888.3027
Class:	II
Product Codes:	PML NKB KWP
Primary Predicate:	KYPHON HV-R® Fenestrated Screw Cement, CD Horizon® Fenestrated Screw Set (K152604)
Additional Predicates:	PERLA®TL Posterior Osteosynthesis System (K213470), TEKTONA HV US Bone Cement (K122175), NEO Pedicle Screw System™ (K212489), G21 Cement & VADER Pedicle Screw System (K200596)

Indications For Use:

PERLA® TL System

The PERLA® TL system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- degenerative disc disease;
- spondylolisthesis;
- fracture;
- dislocation;
- scoliosis;
- kyphosis;
- spinal tumor;
- and failed previous fusion (pseudarthrosis).

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the PERLA® TL system is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PERLA® TL system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

When used in conjunction with TEKTONA® HV US bone cement system, the PERLA®TL system is intended to restore the integrity of the spinal column even in the absence of fusion for a limited period of time, in patients whom life expectancy is of insufficient duration to permit achievement of fusion in advanced stage of thoracic and lumbar spine tumors. The PERLA®TL 35mm to 60mm lengths Screws augmented used with TEKTONA® HV US bone cement system are intended to be used at spinal levels where the structural integrity is not severely compromised.

TEKTONA® HV US Bone Cement

TEKTONA® HV US Bone Cement is indicated for the treatment of pathological fractures of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

When used in conjunction with PERLA®TL system, TEKTONA® HV US Bone Cement is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. PERLA®TL Screws augmented with TEKTONA® HV US Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Device Description:
The PERLA® TL System consists of a range of screws, rods, set screws, hooks, rod connectors and cross-connectors. These connecting components can be rigidly locked to the rod in a variety of configurations to be adapted for the individual case. The PERLA® TL System is manufactured from medical grade titanium alloy and medical grade cobalt chromium conforming respectively to standards ASTM F136 and ASTM F1537.

The PERLA® TL System is identical to the previously cleared version, however this submission includes the additional option to use bone cement with the fenestrated screws.

Mendec Spine HV System (TEKTONA HV US Bone Cement) is highly viscous, radio-opaque acrylic resins (PMMA based) for percutaneous vertebroplasty or kyphoplasty. Mendec Spine HV System holds the powder and liquid components separately within a closed syringe-like device that serves as a mixing chamber. The device is packaged in unitary PVC-blister with tray, sealed with Tyvek lid, which is placed in an aluminum bag. The device is sold disposable and sterile.

Predicate Device:
Spineart submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, PERLA® TL System is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate:	TEKTONA HV US Bone Cement (K122175)
Additional Predicate:	PERLA®TL Posterior Osteosynthesis System KYPHON HV-R® Fenestrated Screw Cement, CD Horizon® Fenestrated Screw Set (K152604) NEO Pedicle Screw System™ (K212489) G21 Cement VADER® pedicle System (K200596)

Performance Testing Summary:
Bone cement usability testing (Usability Testing, Cement Injection Time Testing, and Cement Flow, Bolus Formation, and Screw Removal from Bone Cement Testing) was conducted to validate the use of the Perla® TL System used with bone cement.

Substantial Equivalence:
The subject devices were demonstrated to be substantially equivalent to the predicates cited in the table above with respect to indications, design materials, function, manufacturing, and performance. The non-clinical tests performed by the company included bone cement usability testing and screw removal testing was conducted to validate the use of the Perla® TL System used with bone cement.

Conclusion:
The subject device and the predicate(s) devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in

this submission demonstrate substantial equivalence to the predicate devices listed above. PERLA® TL System is as safe, as effective, and performs as well as, or better, than the predicate devices.