Lento Medical Innovation, Inc.
% Mr. David Schlerf
V.P., CQR
15110 Northwest Freeway, Suite 150
HOUSTON TX 77040

May 4, 2021

Re: K202521
Trade/Device Name: PtoleMedic System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 15, 2021
Received: March 19, 2021

Dear Mr. Schlerf:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name

Lento "PtoleMedic System"

Indications for Use *(Describe)*

The PtoleMedic System is an on-line orthopedic surgical planning software system. MRI images supply data sufficient to allow accurate modeling of anatomy for on-line surgical planning before knee joint replacement surgery. The surgeon preoperatively plans, reviews, adjusts and orients implant images to select implant size and create an idealized surgical plan for the first bony cuts only.

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 Per 21 CFR 807.92

SUBMITTER

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Contact Person:
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Prepared:
April 30, 2021

SUBMISSION DEVICE

Name of Device:
PtoleMedic System, Release 1.3.x

Common or Usual Name:
Surgical Planning Software

Product Name:
PtoleMedic System – Surgical Planning Software

Regulatory Class:
Class II

Product Code:
LLZ.

PREDICATE DEVICE

Somersault Vault System, K124051
The predicate device was never the subject of a design-related recall.

REFERENCE DEVICE

A reference device was used in this submission, Materialise N.V., **SurgiCase System**, K113599
The reference device was never the subject of a design-related recall.

DEVICE DESCRIPTION

Per Code of Federal Regulation:
Sec. 892.2050 - Medical Image Management and Processing System

§ 892.2050
Medical image management and processing system
(a) *Identification.* A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions may include semi-automated measurements or time-series measurements.

The ***PtoleMedic System*** software described here utilized an FDA Guidance Document for industry called "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005". This guidance helped determine submission content and provided a determination of a "MODERATE" level of safety concern for the software. Improper use of software planning or processing could result in harm requiring medical intervention to correct.

The ***PtoleMedic System*** software access is only available via a web/cloud-based software interface. The program is a surgeon-directed surgical case Planning package primarily but not exclusively directed at total joint replacement and closely related orthopedic indications.

After completing secure log-in, the user registers, enters case information, requests MRI images, specifies implant size and parameters, sets orientation requirements, reviews expected outcome positioning, and ultimately authorizes the desired surgical plan.

Once the case is physician authorized, additional Lento Medical Innovation engineering review of the case requirements begin converting the physician recommended implant plan into personalized surgical instruments to reproduce the physician created plan. Only Lento Medical Innovation personnel may access engineering modules of the ***PtoleMedic System*** software. The engineering staff uses proprietary software to convert the plan parameters into manufacturing output. Manufacturing output means anatomically personalized models to help the surgeon visualize the bony cuts' physical orientation. Trained engineers then convert style/brand of implant, sizing requirements, component orientation, and limb alignment requirements into output to make anatomically fitted models for exclusive use by the surgeon and the specifically named patient.

INDICATIONS FOR USE

"The PtoleMedic System is an on-line orthopedic surgical planning software system. MRI images supply data sufficient to allow accurate modeling of anatomy for on-line surgical planning before knee joint replacement surgery. The surgeon preoperatively plans, reviews, adjusts and orients implant images to select implant size and create an idealized surgical plan for the first bony cuts only."

The Indications for Use statement for the **Somersault Vault System,** while not identical in scope, includes surgical case planning and digital file output suitable for CNC machining. The Vault System provided planning for additional major joint locations, whereas Lento's PtoleMedic System is limited to total knee replacement procedures only and the creation of anatomic models representative of the planned bony resections for use as a visual aid.

The PtoleMedic System device, the predicate device, and the reference device share a common intended use. All are for orthopedic surgical joint replacement planning, and all systems are classified within ProCode; LLZ.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

As with the Somersault Vault System, the ***PtoleMedic System*** provides restricted, secure web-based access for total joint replacement surgical planning. Both systems use digital DICOM-based data from pre-operative MRI scans of the operative limb, including the spatial location of the hip, knee, and ankle complex.

Both planning systems can create accurate anatomic models of the distal femur and tibia, representing the planned positioning of the bony cuts needed to align the implants the surgeon has chosen to use. Both systems are surgeon-controlled and directed. Both systems allow the surgeon to identify their preferred implant brand for use in Planning. Finally, the surgeon authorizes the plan and, if requested, a custom anatomic model of the resultant bone cuts may be supplied.

Both systems' software performance data are based upon current software development methodology, including defined bench and phantom models. Verification and Validation activities are identical and fully demonstrate planned objective and subjective test conditions are satisfactory. The V&V testing results on the Vault System and the ***PtoleMedic System*** provided consistent planning accuracy and performance.

Predefined Functional requirements, meeting ***PtoleMedic System*** Software Requirement Specifications (SRS), and Software Design Specifications (SDS) demonstrate all attributes and traceability activity, meet US-FDA General Principles of Software Validation and EU-MDR requirements for CE Marking.

Software development processes conform with FDA Guidance; "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005".

Level of Concern determination for both the Vault System and the PtoleMedic System is "MODERATE" as determined by FDA for the Vault System. Safety concerns identified during

risk/hazard analysis follow ISO 14971:2017 and EN/ISO-13485:2016. Validation includes accuracy, repeatability, and stress testing per FDA's Guidance for Software Contained in Medical Devices. Software testing addressed the following areas of function as related to development engineers and users.

- Test Planning
- System Requirements Tests (SRS)
- Acceptance Test Execution
- Structural Test Identification
- Functional Test Identification
- Unit (Module) Tests (SDS)
- Integration Tests (High Level) (SDS)
- Unit (Module) Testing
- System Integration Testing
- Functional Testing
- System Testing
- Test Result Evaluation
- Error Evaluation/Resolution
- Traceability Review and Analysis
- Final Test Reports

The ***PtoleMedic System*** software meets its defined requirements and specifications. All identified test faults are corrected, mitigated, or eliminated as or if they occurred. No test variances remain. Final assessment using a software requirements matrix demonstrated software compliance within the scope of the testing. The ***PtoleMedic System*** meets all software requirements. All testing confirms system input equals system output.

The ***PtoleMedic System*** software is to be marketed in the USA as surgical planning software. The predicate comparison software system (Vault System) and the other reference software system(s) offered by Materialise, NV. Both software systems take advantage of existing PC-type hardware, browsers, and internet access with high-resolution viewers. Both systems utilize digital DICOM images to view, plan, print, and produce models and physical representations of the planned bony resections.

The technology utilized in creating and controlling the ***PtoleMedic System*** software is well understood. Several orthopedic software companies, Somersault, in particular, promote a virtually identical product. The equivalent software systems also offer orthopedic surgical planning software wherein a digital CT/MRI data file provides the basis for a prescriptive order for patient-specific anatomic information (Personalized Surgical Plan). The ability to identify specific anatomic features and landmarks allows for accurate sizing, positioning, and marking tissue before cutting based on a patient's unique anatomy.

System Similarities:
The ***PtoleMedic System*** and the equivalent ***Vault System*** use an image-based approach to interactive pre-operative Planning, visualization, printing with the potential creation of accurate patient-specific pre and post-resection models. The ***PtoleMedic System***, the Vault System, and the Materialise software share the following fundamental characteristics and functions:

- Computer/browser/internet based
- Support for orthopedic Total Knee Replacement (TKR)
- Utilize MRI DICOM based digital images for an accurate depiction of individual anatomy, incorporating a traditional mechanical axis alignment philosophy
- An individualized plan for each patient
- Comparable cyber-secure systems for enrollment, upload/download, presurgical Planning, visualizing, implant alignment and sizing, annotating and editing medical image data
- Controllable alignment variables include sizing, rotation (IR/ER), flexion, extension & varus/valgus angles
- The surgeon created and approved plans to set the femoral and tibial resection locations

All systems can utilize MRI-based images to size, orient, and position various implant components and locate the desired bony tissue resections. Each software system orients the distal femur and proximal tibia's primary bone cut to facilitate the chosen implants' placement. All systems use DICOM compliant digital image data for Planning, image display, overlay manipulation, and machine code processing to produce anatomic models if requested.

System Differences:
- ***Vault System*** supports all major joint Planning.
- ***PtoleMedic System*** is focused on Total Knee Replacement procedures only
- ***Materialise System*** is brand specific.
- ***PtoleMedic System*** and ***Vault System*** are brand agnostic.
- ***Materialise System*** requires the creation of 3D models for Planning and whole image segmentation.
- ***PtoleMedic System*** utilizes multi-plane 2D slices to establish spatial orientation and resection angulation and location

Substantial Equivalence Table

Feature	*Lento PtoleMedic System*	Somersault Vault System	Materialise Reference System	SE.
Intended Use:	The PtoleMedic System is an on-line orthopedic surgical planning software system. MRI images supply data sufficient to allow accurate modeling of anatomy for on-line surgical Planning before joint replacement surgery. The surgeon preoperatively plans, reviews, adjusts, and orients implant images to select implant size and create an idealized surgical plan for the first bony cuts only.	The Vault **System** is intended for use as a software interface and image manipulation system for the transfer of imaging information from a medical scanner such as Computerized Axial Tomography **(CT)** or Magnetic Resonance Imaging (MRI). It is also intended as pre-operative software for simulating/evaluating implant placement and surgical treatment options. The physician chooses the output data file for printing and/or subsequent use in **CAD** modeling or CNC/Rapid-prototyping.	The **SurgiCase** System is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also intended as pre-operative software for simulating/ evaluating implant placement and surgical treatment options.	**Yes**
Classification:	**Class II**	**Class II**	**Class II**	**Yes**
ProCode:	**LLZ**	**LLZ**	**LLZ**	**Yes**
Internet access required:	**YES**	**YES**	**YES**	**Yes**
Runs on Cloud Server:	**YES**	**YES**	**YES**	**Yes**
Digital Overlay Implants:	**YES**	**YES**	**YES**	**Yes**
Pre-operative Planning:	**YES**	**YES**	**YES**	**Yes**
A plan created, reviewed & authorized by surgeon:	**YES**	**YES**	**YES**	**Yes**
Imaging modality	**DICOM**	**YES**	**YES**	**Yes**
Cautions:	**Uploaded images must pass QC for Image quality and anatomic detail**	**SAME**	**SAME**	**Yes**
Femoral Resection Level:	**Based on anatomic features, mechanical alignment & posterior referencing**	**SAME**	**SAME**	**Yes**
Tibial Resection Level:	**Based on anatomic features, mechanical alignment**	**SAME**	**SAME**	**Yes**
Flex, extension, tibial slope:	**Based on anatomic features, mechanical alignment**	**SAME**	**SAME**	**Yes**
Overall limb alignment:	**Based on mechanical alignment**	**SAME**	**SAME**	**Yes**
Alignment Options:	**Mechanical Alignment & Neutral Boundary Alignment (NBA)**	**Mechanical Alignment**	**Mechanical Alignment**	**Yes**
Implant sizing:	**Based on anatomic features**	**SAME**	**SAME**	**Yes**
Verification tools:	**Intraoperative**	**SAME**	**SAME**	**Yes**
Implant Types supported:	**A physician identified, Non-custom implant**	**SAME**	**SAME**	**Yes**
K-Number	**K202521**	**K124051**	**K113599**	**Yes**

CONCLUSION

Lento Medical Innovation, Inc. believes the documentation submitted demonstrates the ***PtoleMedic System*** is as safe and effective as the predicate systems. No new indications, uses, capabilities, or technological characteristics are proposed, suggested, or requested. All requested uses for the ***PtoleMedic System*** software are already available from other manufacturers offering legally marketed devices in the USA and EU.

Predefined Functional requirements, meeting ***PtoleMedic System*** Software Requirement Specifications (SRS), and Software Design Specifications (SDS) demonstrate all attributes and traceability activity, meet US-FDA General Principles of Software Validation and EU-MDR requirements for CE Marking.

Software development processes conform with FDA Guidance; "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005".

The Food and Drug Administration cleared the Vault System with a "MODERATE" level of concern. The PtoleMedic System is identical. The risk/hazard analysis follows ISO 14971:2017 and EN/ISO-13485:2016 and the FDA guidance for the level of concern determination.

Verification and Validation activities include accuracy, repeatability, and stress testing per FDA's Guidance for Software Contained in Medical Devices. Software testing addressed the following areas of function as related to development engineers and users.

- Test Planning
- System Requirements Tests (SRS)
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