November 26, 2019

LimaCorporate
% David McGurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K190911
Trade/Device Name: Physica KR Liner and SMR Reverse Humeral Liner
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, HRY, PHX, KWS, MBF, KWT
Dated: October 29, 2019
Received: October 29, 2019

Dear David McGurl:

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 Ting Song, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K190911

Device Name

Physica KR Liner and SMR Reverse Humeral Liner

Indications for Use *(Describe)*

Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Physica knee system is intended for cemented fixation

The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant;
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral

stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.

The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

On the glenoid side, the fixation of the all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	Use	
A	R			Cem	Not Cem
•	•	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X	
•	•	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X
•		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X
•	•	SMR Reverse Humeral Body	Ti6Al4V	X	X
•	•	Humeral Extension	Ti6Al4V	X	X
•		SMR Humeral Heads (Standard*, CTA)	CoCrMo	X	X
•		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X
•		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	•	SMR Glenospheres	CoCrMo		X
	•	SMR Connectors*	Ti6Al4V		X
	•	Reverse Liners	UHMWPE	X	X
•		SMR Cemented Glenoids	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoids	UHMWPE	X	
•	•*	SMR Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	•	SMR Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
•	•	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*
•	•	SMR TT Metal Back Peg	Ti6Al4V	X	X
•		SMR Metal Back Liner	UHMWPE	X*	X*
•*	•	SMR Bone screws	Ti6Al4V		X
Material Standards					
Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)					

A= Anatomic / R=Reverse

***NOTE:**

- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **SMR lateralized connectors are not indicated for use with glenoid bone grafting techniques.**
- **In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **If a SMR Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR Hybrid Glenoid Reverse Baseplate. The SMR Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.**

- **The Dia. 50, 52 and 54 mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**
- **The Dia. 52 and 54 mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**

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.

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510(K) SUMMARY

Device Trade Name: Physica KR Liner and SMR Reverse Humeral Liner

Manufacturer:
LimaCorporate
Via Nazionale, 52
33038 Villanova di San Daniele del Friuli
Udine, Italy

Contact:
Mr. Roberto Gabetta
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Prepared by:
Mr. Dave McGurl
Director, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NE, Suite 1000
Washington, DC 20005
Phone: 202.552.5800
dmcgurl@mcra.com

Date Prepared: November 26, 2019

Classification:
21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

21 CFR 888.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis.

21 CFR 888.3660 Shoulder joint metal/polymer semi-constrained cemented prosthesis.

21 CFR 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

21 CFR 888.3650 Shoulder joint metal/polymer non-constrained cemented prosthesis

Class: II

Product Code: JWH, HRY, PHX, KWS, MBF, KWT

Predicate Devices:
Physica KR Knee System (K141934)
SMR Shoulder System (K110598, K142139, K163397)

Indications for Use:

Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Physica knee system is intended for cemented fixation.

The SMR Shoulder System is intended for partial or total, primary or revision shoulder joint replacement.

The SMR Anatomic Shoulder System is indicated for partial or total, primary or revision shoulder joint replacement in patients suffering from disability due to:

- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- inflammatory degenerative joint disease such as rheumatoid arthritis;
- treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- revision of a failed primary implant;
- cuff tear arthropathy (CTA Heads only);
- glenoid arthrosis without excessive glenoid bone loss: A1, A2 and B1 according to Walch classification (SMR Hybrid Glenoid only).

The SMR Reverse Shoulder System is indicated for primary, fracture or revision total shoulder replacement in a grossly rotator cuff deficient joint with severe arthropathy (disabled shoulder). The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Hybrid Glenoid Reverse Baseplate must not be used in cases of excessive glenoid bone loss and/or when bone graft is needed.

The Modular SMR Shoulder System allows the assembly of components in various humeral and glenoid constructs. The constructs are intended for cemented and uncemented use as specified in the following table.

In the Anatomic shoulder the humeral construct consists of the humeral stem, the humeral body, the adaptor taper and the humeral head. In the Reverse shoulder the humeral construct consists of the humeral stem, the reverse humeral body and the reverse liner. On the humeral side the fixation of the humeral stem determines if the construct is cemented or uncemented.

The Anatomic glenoid construct consists of an all polyethylene glenoid, a polyethylene glenoid with metal peg or a metal back assembled with a liner; the Reverse glenoid consists of a metal back/connector/glenosphere construct or of a peg/baseplate/glenosphere construct.

On the glenoid side, the fixation of the all polyethylene glenoid, the polyethylene glenoid with metal peg or the metal back determines if the construct is cemented or uncemented.

System		Components	Material	Use	
A	R			Cem	Not Cem
•	•	SMR Stems (Cemented, Cemented Revision)	Ti6Al4V	X	
•	•	SMR Stems (Cementless Finned, Cementless Revision)	Ti6Al4V		X
•		SMR Humeral Bodies (Trauma, Finned)	Ti6Al4V	X	X
•	•	SMR Reverse Humeral Body	Ti6Al4V	X	X
•	•	Humeral Extension	Ti6Al4V	X	X
•		SMR Humeral Heads (Standard*, CTA)	CoCrMo	X	X
•		SMR Adaptor Tapers (Neutral, Eccentric)	Ti6Al4V	X	X
•		SMR CTA Head Adaptor for Reverse Humeral Body	Ti6Al4V	X	X
	•	SMR Glenospheres	CoCrMo		X
	•	SMR Connectors*	Ti6Al4V		X
	•	Reverse Liners	UHMWPE	X	X
•		SMR Cemented Glenoids	UHMWPE	X	
•		SMR 3 Pegs Cemented Glenoids	UHMWPE	X	
•	•*	SMR Hybrid Glenoid	UHMWPE+Ti6Al4V+Ta	X	X
	•	SMR Hybrid Glenoid Reverse Baseplate + Screw	Ti6Al4V		X
•	•	SMR Metal Back Glenoids	Ti6Al4V+PoroTi	X*	X*
•	•	SMR TT Metal Back Baseplate	Ti6Al4V	X*	X*
•	•	SMR TT Metal Back Peg	Ti6Al4V	X	X
•		SMR Metal Back Liner	UHMWPE	X*	X*
•*	•	SMR Bone screws	Ti6Al4V		X
Material Standards					
Ti6Al4V (ISO 5832-3 - ASTM F1472) - **CoCrMo** (ISO 5832-12 - ASTM F1537) – **UHMWPE** (ISO 5834-2 - ASTM F648) - **PoroTi Titanium Coating** (ASTM F1580) - **Ta** (ISO13782 - ASTM F560)					

A= Anatomic / R=Reverse

***NOTE:**

- **In the US, the SMR Metal Backed Glenoid/Liner construct, used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws.**
- **The SMR Metal Backed Glenoid/Connector/Glenosphere construct, used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**
- **SMR lateralized connectors are not indicated for use with glenoid bone grafting techniques.**
- **In the US the SMR TT Metal Back Baseplate used as part of the SMR Anatomic Shoulder Replacement, is intended for use with bone cement and should be used without bone screws; while when used as part of the SMR Reverse Shoulder replacement, is intended for uncemented use with the addition of screws for fixation.**

- **If a SMR Hybrid Glenoid is in place and revision to a reverse prosthesis is required, the patient can be revised by removing the polyethylene baseplate, leaving the metal peg in place and by connecting it to the SMR Hybrid Glenoid Reverse Baseplate. The SMR Hybrid Glenoid Reverse Baseplate is intended for uncemented use with the addition of screws for fixation.**
- **The Dia. 50, 52 and 54 mm Humeral Heads with + 3mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**
- **The Dia. 52 and 54 mm Humeral Heads with + 2mm increased height cannot be coupled to the Long Adaptor Tapers (both concentric and eccentric).**

Device Description:
The Physica System is a total knee system and the SMR Reverse is a reverse shoulder system.

The purpose of the Special 510(k) is to add an alternative sterilization method for the Physica KR Liner and SMR Reverse Humeral Liners. Both systems utilize conventional (non-crosslinked) UHMWPE liners (ISO 5834-2 ASTM F648). The liners can be sterilized using a minimum gamma radiation dose of 25 kGy.

Substantial Equivalence:
The Physica KR Liner and SMR Reverse Humeral Liner is substantially equivalent to the predicate devices cited on the previous page with respect to indications, design, function, and performance.

Preclinical Testing:
The following activities were performed:

- Sterilization validation
- UHMWPE Characterization
- Mechanical Testing

Clinical Testing:
Clinical testing was not necessary to support equivalence.

Conclusion:
The Physica KR Liner and SMR Reverse Humeral Liner possesses the same intended use and technological characteristics as the predicate devices. Therefore, the Physica KR Liner and SMR Reverse Humeral Liner is substantially equivalent for its intended use.