



June 10, 2026

Movmedix S.A.S.
Luisa Arcos
Regulatory Affairs Manager
5 Rue de la Fontaine
Arc-sur-Tille, Bourgogne-Franche-Comte 21560
France

Re: K253115
Trade/Device Name: LARS ACJ
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN, MBI
Dated: May 7, 2026
Received: May 7, 2026

Dear Luisa Arcos:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

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.

K253115

?

Please provide the device trade name(s).

?

LARS ACJ

Please provide your Indications for Use below.

?

The LARS® ACJ is indicated to provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions. The LARS® ACJ implant components are for single use only.

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

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

?

510(k) Summary

Device: LARS ACJ

Applicant/Manufacturer: Movmedix S.A.S.
Company Address: 5 rue de la Fontaine
 Arc Sur Tille, Bourgogne-Franche-Comte, FR 21560
Contact Person: Luisa Arcos
Date Summary Prepared: June 8, 2026
Trade Name: LARS ACJ
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code(s): HTN (washer, bolt nut) & MBI (fastener, fixation, nondegradable, soft tissue)
Device Class: Class II
Regulation Number(s): 21 CFR 888.3030 & 21 CFR 888.3040

Predicate Devices:

Trade name	Primary Predicate LARS AC Band	Secondary Predicate LOCKDOWN Acromioclavicular (AC)
510(k)	K190143	K091207
Manufacturer	MOV MEDIX SAS (FR) (previously LARS SA)	LOCKDOWN Medical Ld. (UK) (previously Surgicraft)
Class	II	II
Product Code / Name	1) HTN / washer, bolt nut 21 CFR 888.3030 / Single/multiple component metallic bone fixation appliances and accessories.	1) HTN / washer, bolt nut 21 CFR 888.3030 / Single/multiple component metallic bone fixation appliances and accessories.
Classification Regulation / Name	2) MBI / fastener, fixation, nondegradable, soft tissue 21 CFR 888.3040 / Smooth or threaded metallic bone fixation fastener	

Device Description

The LARS[®] ACJ (Ligament Advanced Reinforcement System - Acromioclavicular Joint) is a system device predicated on the LARS AC Band device system previously cleared under K190143. As in the original device it involves a knitted PET surgical scaffold in the form of a band intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular disruptions. The main differences involve:

- the main knitted fabric section being wrapped on to itself along its length and sewed together to provide a cylindrical band instead of a double layered flat band in the original design,

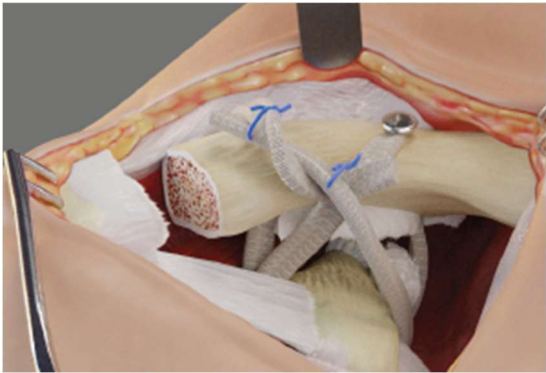
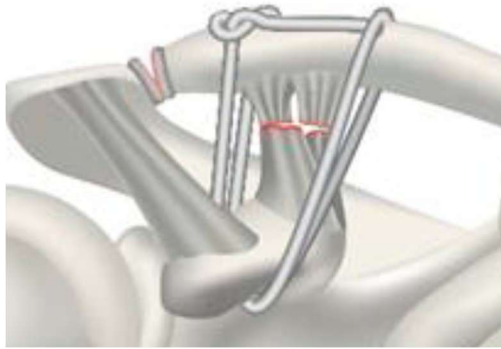
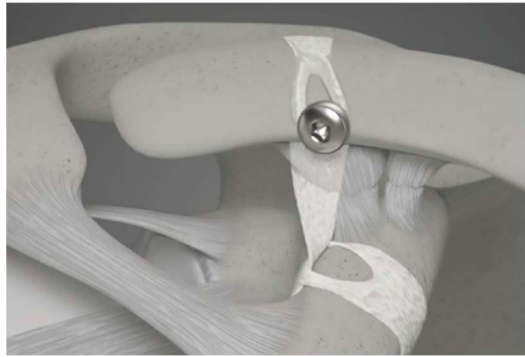
- an additional larger size of mesh implant to complement the original single size, and new screw fixation components and instruments to provide for a screw fixation method instead of the direct bone fixation method in the original design,
- either ends of the bands now include traction threads to facilitate passing the bands through bone tunnels in the surgical procedure per the new screw fixation to the clavicle as compared to a loop at one end and the cut band at the other end in the original design per its direct attachment method (looping attachment around the clavicle).




Comparison of intended use - indications for use

Proposed LARS ACJ	Primary Predicate LARS AC Band	Secondary Predicate LOCKDOWN Acromioclavicular (AC)
<p>The LARS® ACJ device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p> <p>The LARS™ ACJ implant components are for single use only.</p>	<p>The LARS® Tissue Reinforcement Band AC device is indicated to provide fixation during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p> <p>The LARS® Tissue Reinforcement Band AC device is indicated for single use only.</p>	<p>The LOCKDOWN™ Acromioclavicular (AC) device is indicated to provide fixation</p> <p>during the healing process following a syndesmotic trauma, such as fixation of acromioclavicular separations due to coracoclavicular ligament disruptions.</p>

The intended-use/indications are unchanged from the LARS AC Band predicate and is the same as in the LOCKDOWN predicate.

Comparison of Technological Characteristics

	Proposed LARS ACJ	Primary Predicate LARS AC Band	Secondary Predicate LOCKDOWN Acromioclavicular (AC)
<p>Principle of Operation</p>	<p>Suspensory function between the coracoid and clavicle: The mesh implant is looped under the coracoid process and attached to either side to the clavicle. The attachment to the clavicle is per each end of the mesh implant being pulled through holes made in the clavicle to each side of coracoid and secured with two LARS Screw implants.</p> <p>For further stability and support, the remaining end on the medial side is looped back under the coracoid process in a figure-of-8 and knotted to the free end on the lateral side. The knotted ends are secured together with sutures and the remaining lengths beyond the sutured knot are resected.</p> 	<p>Suspensory function between the coracoid and clavicle: The mesh implant is double looped under the coracoid process. It attaches to the clavicle by being looped around the clavicle to each of the medial and lateral sides of the clavicle. The ends of the mesh implant are fixed together on the lateral side of the clavicle by one end being looped under and through the other end's eyelet. It is then passed along the top of the clavicle and tucked under the other loop on the medial side of the clavicle and further secured with sutures to the top of the clavicle. The excess lengths are resected.</p> 	<p>Suspensory function between the coracoid and clavicle: The leading end of the mesh implant is looped (single loop) under the coracoid through the eyelet of the end of the mesh implant and passed around the posterior side of the clavicle and over the top area of the clavicle (single loop) with the leading eyelet being secured to anterior face of the clavicle with a single screw/washer.</p> 

	Proposed LARS ACJ	Primary Predicate LARS AC Band	Secondary Predicate LOCKDOWN Acromioclavicular (AC)
Material (implants)	<p><u>Mesh</u>: polyethylene terephthalate (PET) <u>Screw fixation</u>: Titanium</p>	<p><u>Mesh</u>: polyethylene terephthalate (PET)</p>	<p><u>Mesh</u>: polyethylene terephthalate (PET) <u>Screw fixation</u>: Stainless Steel and Titanium screws and washers</p>
Design – Mesh Implant	<p><u>Mesh Implants (two sizes)</u>:</p> <ul style="list-style-type: none"> - Identically the same mesh knitted mesh fabric construction as the LARS AC Band mesh implant with modified feature as noted in following points: - LAC20: 4mm Ø by 370 - 430mm length - LAC30CK: 5mm Ø by 450 - 475mm length - Implantable section: non-absorbable Polyethylene Terephthalate (PET) knit & polyester sewing thread - Resection section to facilitate placement: Ultra High Molecular Weight Polyethylene (UHMWPE) traction threads and PET ligature threads - The ends are cut to length (i.e. removal of Resection section and excess ends of Implantable section) by the surgeon after placement to achieve the desired reduction. - Designed for fixation/attachment by double loops under the coracoid and clavicle with fixation through bone holes to either side of the clavicle with interference screw implants in each hole (i.e. 2 screws total). 	<p><u>Mesh Implant (one size)</u>:</p> <ul style="list-style-type: none"> - Flat 6mm wide by 400mm length - non-absorbable Polyethylene Terephthalate (PET) knit & polyester sewing thread - Eyelet at one end for loop attachment around clavicle - Other end is cut to length by surgeon after placement to achieve the desired reduction <p>Designed for fixation/attachment by double loops under the coracoid and clavicle and attachment of each of the mesh implant ends to each other itself via the eyelet of the mesh implant with additional sutures of the length after the eyelet along the top of the clavicle to each side of coracoid.</p> 	<p><u>Mesh Implants (multiple sizes)</u>:</p> <ul style="list-style-type: none"> - Flat 11mm wide by 4 to 20cm in lengths in 1 cm increments - non-absorbable PET knit fabric - multiple length sizes to achieve the desired reduction as determined during placement - Two eyelets (one at each end) – one for loop attachment around coracoid and other to attach to one side of the clavicle with one screw/washer. 

	Proposed LARS ACJ	Primary Predicate LARS AC Band	Secondary Predicate LOCKDOWN Acromioclavicular (AC)
Design – Screw Implants	<p>Screw Implants (Titanium Ti-6Al-4V ELI):</p> <ul style="list-style-type: none"> - 4.7 mm Ø x 15 mm length, cannulated, conical - 5.2 mm Ø x 15 or 20mm length, cannulated, conical - Shoulder-less conical interference type screws. 	Not Applicable.	<p>Screw/Washer Implants (Ti-6Al-4V ELI or Stainless Steel):</p> <ul style="list-style-type: none"> - Screws: 3.5mm Ø x 14 to 40mm length in 1 mm increments - Washer: OD 7 to 9mm in 1mm increments <p>Attaches mesh implant loop on clavicle (not in hole)</p>
Cross-section	Fabric wrapped onto itself and sewed together to form a cylindrical section	Double layers of fabric sewed together to form a flat section	Flat section
Surgical Technique / Instrumentation	<p>For placing/guiding the mesh implant around the the coracoid and clavicle:</p> <ul style="list-style-type: none"> - Acromio-clavicular guide - Wire Loop - K-wire <p>For screw fixation</p> <ul style="list-style-type: none"> - Drill bit Ø 3,5 x 150 mm & 4,5 x 150 mm - Drilling Guide <p>Hexagonal screwdriver 3.5 mm</p>	<p>For placing/guiding the mesh implant around the the coracoid and clavicle:</p> <ul style="list-style-type: none"> - Acromio-clavicular guide - Wire Loop <p>K-wire</p>	<p>For placing/guiding the mesh implant around the the coracoid and clavicle:</p> <ul style="list-style-type: none"> - Tubular Introducer (Medium) - Tubular Introducer (Large) - Loop Tensioner <p>For screw fixation:</p> <ul style="list-style-type: none"> - AO Handle with Quick Coupling - AO Screwdriver Shaft Ø2.5mm - Screw Holding Sleeve - Depth Gauge <p>Drill Sleeve Ø2.5mm & Tap Sleeve Ø3.5m</p>
Sterilization	Mesh & Screws: electron beam radiation	Mesh: electron beam radiation	Mesh and Screws/washer: gamma radiation
Shelf-life	5 Years	5 Years	5 Years

The proposed LARS ACJ has the same main principle of operation as both the LARS AC Band and the LOCKDOWN predicate as a suspensory device between the coracoid and the clavicle in providing the same common intended use. The main implantable section of the mesh implant is made with identical knitted PET fabric sewn into its shape with a polyester thread as the LARS AC predicate.

The main difference as compared to the LARS AC Band is the new screw fixation method. However, this is equivalent to that in that in the LOCKDOWN predicate which also similarly provides screw fixation to the clavicle for the same intended use.

As to the additional features of the proposed LARS ACJ, these are sizing differences or engineering implementation differences appropriate to each design's particular fixation or attachment features without changing their common equivalent suspensory function using a mesh implant. The differences in implementation have been shown to being substantially equivalent as assessed by the non-clinical testing:

Biological Evaluation:

All biocompatibility safety requirements were met per ISO 10993-1:2018 and the FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (2023)*,

Sterilization, Pyrogenicity, Packaging, and Shelf-Life:

These were all revalidated similarly as in the LARS AC Band predicate. Radiation sterilization was validated per ISO 11137-1/2, pyrogenicity per USP 151, and the sterile packaging per ISO 11607-1:2019 for a shelf-life of 5 years as in the two predicates. The instrument cleaning and sterilization specifications were also revalidated for the additional screw fixation related instruments.

Performance Bench Test:

These included the following verification tests:

- mechanical characterization of the LARS screws per ASTM F543-23 (Standard Specification and Test Methods for Metallic Medical Bone Screws)
- screw – mesh implant resistance to pull out (pullout strength of mesh implant out of screw interference fixation)
- tensile testing – comparison to LARS AC Band: the result showed that the predicate LARS AC Band is of equivalent strength as the same size LARS ACJ mesh implant (LAC 20)
- Tensile strength – effects of aging (accelerated); the result showed that there were no changes in tensile strength of the LARS ACJ Mesh Implants after aging
- Sutured Ligament Testing – resistance of the ends of the mesh implant sutured together in a simulated looped and screw attachment construct as per the proposed attachment/fixation method
- Fatigue testing: this test verified cyclic physiological loading and post-fatigue strength
- MRI compatibility testing showing that the implants are MRI Conditional as indicated in the labelling.

Conclusion on Substantial Equivalence

The LARS ACJ has the same intended use and indications as the predicates utilizing the same main methods/technology including the same material for the mesh implant (the implantable section) as the LARS AC Band predicate and screw fixation components similarly as in the LOCKDOWN predicate. The main differences were found to be either of a sizing range nature or related to engineering implementation differences appropriate to each design's particular fixation or attachment features and do not raise any different questions of safety and effectiveness compared to the predicates. Performance testing demonstrated that the subject device is as safe and effective as compared to the predicates.

In conclusion, the LARS ACJ can be found to be substantially equivalent to the predicates.