

**K223509 Compremium Compartment Compressibility Monitoring System (CPM#1)**Apr 14, 2023  
143 days to decisionK223509 · Product code: **LXC** · Orthopedic  
Source: <https://www.510kdatabase.net/k223509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Pressure, Intracompartmental (LXC)
Date received	Nov 22, 2022
Decision date	Apr 14, 2023
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

Company	<b>Compremium AG</b>
Location	Muri, CH
Contact	Vincent Baumann
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

Consulting firm	<b>Medidee Services, LLC</b>
Contact	Philippe Etter

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT05483946****SWISS CLEARANCE - Compartment Compressibility Monitoring Using CPM#1**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	7 patients (actual)
Study sites	1 site
Condition studied	Compartment Syndromes
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Nov 1, 2022
Sponsor	Compremium AG (Industry)

**Primary outcome**

Inter-operator reproducibility with 3 raters

**Secondary outcome**

Intra-operator reproducibility

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05483946](https://clinicaltrials.gov/study/NCT05483946)