

K143158 Xenco Medical Lumbar Interbody SystemMar 20, 2015
137 days to decisionK143158 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k143158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 3, 2014
Decision date	Mar 20, 2015
Days to decision	137 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xenco Medical, LLC
Location	San Diego, CA, US
Contact	Gustavo Prado
510(k) history	16 submissions · 16 cleared · 2014-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k143158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026