

K133482 SILC FIXATION SYSTEMMay 21, 2014
189 days to decisionK133482 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k133482/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Nov 13, 2013
Decision date	May 21, 2014
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Globus Medical, Inc.
Location	Audubon, PA, US
Contact	CHRISTINA KICHULA
Website	https://www.globusmedical.com
510(k) history	171 submissions · 168 cleared · 2003-2026

Globus Medical, Inc. is a publicly traded orthopedic medical device company headquartered in Audubon, Pennsylvania. The company designs, develops, and commercializes products enabling surgeons to promote healing in patients with musculoskeletal disorders. Globus Medical has received FDA 510(k) clearances from total submissions since its first clearance in 2003. The company's regulatory portfolio is dominated by orthopedic devices, representing 98% of all submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued innovation and market presenc...
