

K172417 SILC® Fixation SystemOct 26, 2017
77 days to decisionK172417 · Product code: **OWI** · Orthopedic
Source: <https://www.510kdatabase.net/k172417/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Fixation Cerclage, Sublaminar (OWI)
Date received	Aug 10, 2017
Decision date	Oct 26, 2017
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Globus Medical, Inc.
Location	Audubon, PA, US
Contact	Lori Burns
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...
