

K210912 Excelsius3DAug 12, 2021
136 days to decisionK210912 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k210912/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Mar 29, 2021
Decision date	Aug 12, 2021
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Globus Medical, Inc.
Location	Audubon, PA, US
Contact	Kelly Baker
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...

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Device record: <https://www.510kdatabase.net/k210912/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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