

K171939 ALVUE Balloon Dilation SystemMar 7, 2018
252 days to decisionK171939 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k171939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jun 28, 2017
Decision date	Mar 7, 2018
Days to decision	252 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...