

K243722 Pre-B Seal Lung Biopsy Plug System - 15cm Model (FG0001)Apr 8, 2025
126 days to decisionK243722 · Product code: **OMT** · Anesthesiology
Source: <https://www.510kdatabase.net/k243722/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Absorbable Lung Biopsy Plug (OMT)
Date received	Dec 3, 2024
Decision date	Apr 8, 2025
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Pre-B Seal Lung Biopsy Plug System - 16cm Model (FG0002); Pre-B Seal Lung Biopsy Plug System - 20cm Model (FG0003)

APPLICANT

Company	Selio Medical Limited
Location	Dublin, IE
Contact	Colm McGarvey
510(k) history	1 submissions · 1 cleared · 2025-2025

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