FDA 510(k) Premarket Notification

K232250 SurgiCount+ System

CLEARED

Jan 11, 2024
167 days to decision

K232250 · Product code: **PBZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Processing Device For Estimation Of External Blood Loss (PBZ)
Date received	Jul 28, 2023
Decision date	Jan 11, 2024
Days to decision	167 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Stryker Instruments**
Location	Kalamazoo, MI, US
Contact	Patti Arndt
510(k) history	72 submissions · 72 cleared · 1994-2026