FDA 510(k) Premarket Notification

K202583 BioShield biopsy valve EUS - Linear

CLEARED

Nov 6, 2020
59 days to decision

K202583 · Product code: **ODD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k202583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Retrograde Cholangiopancreatography (ercp) Cannula (ODD)
Date received	Sep 8, 2020
Decision date	Nov 6, 2020
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**STERIS Corporation**
Location	Mentor, OH, US
Contact	Jacqueline Oliver
510(k) history	204 submissions · 202 cleared · 1997-2026