

**K210342 BioShield- ERCP Biopsy Valve, BioShield Irrigator -
Extension Tubing, BioShield Irrigating Adaptor**Sep 3, 2021
210 days to decisionK210342 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k210342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Feb 5, 2021
Decision date	Sep 3, 2021
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026