FDA 510(k) Premarket Notification

CLEARED

K232951 BioShield Biopsy Valve (00711124)

Oct 20, 2023
29 days to decision

K232951 · Product code: **ODC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscope Channel Accessory (ODC)
Date received	Sep 21, 2023
Decision date	Oct 20, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BioShield Biopsy Valve (00711125); BioShield Biopsy Valve (00711126); BioShield Biopsy Valve (00711127); BioShield Biopsy Valve (00711129); BioShield Biopsy Valve (00711135); BioShield Biopsy Valve (00711136); BioShield Biopsy Valve - sterile (00711128); BioShield Irrigator (00711133); BioShield Irrigator (00711137); BioShield Irrigating Adaptor (00711131); BioShield Irrigator - extension tubing (00711134)

APPLICANT

Company	**Steris**
Location	Mentor, OH, US
Contact	Carroll Martin
Website	https://www.steris.com
510(k) history	21 submissions · 19 cleared · 2021-2026

Steris is a leading global provider of products and services supporting patient care with emphasis on infection prevention. The company operates with a manufacturing facility in Mentor, Ohio, and serves hospitals, surgery centers, pharmaceutical manufacturers, and research laboratories worldwide. Steris has received FDA 510(k) clearances from total submissions since 2021. The company specializes in General Hospital devices, which represent 81% of its regulatory submissions. Recent clearances include sterilization systems, chemical indicators, biological indicators, and wa...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k232951/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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