FDA 510(k) Premarket Notification

CLEARED

Mar 8, 2024
177 days to decision

K232826 Articulator Injection Needle (00711807), Articulator Injection Needle (00711810), Articulator Injection Needle - enteroscope (00711808), Carr-Locke Injection Needle (00711811), Carr-Locke Injection Needle (00711812), Carr-Locke Injection Needle (00711813), Carr-Locke Injection Needle (00711814), Carr-Locke Injection Needle (00711822), Carr-Locke Injection Needle (00711823), Carr-Locke Injection Needle (00711824)

K232826 · Product code: **FBK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k232826/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Injection Needle, Gastroenterology-urology (FBK)
Date received	Sep 13, 2023
Decision date	Mar 8, 2024
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

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...