FDA 510(k) Premarket Notification

K220846 CORE-SNARE

CLEARED

Nov 21, 2022
243 days to decision

K220846 · Product code: **FDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k220846/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Snare, Flexible (FDI)
Date received	Mar 23, 2022
Decision date	Nov 21, 2022
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Incore Co., Ltd.**
Location	Daegu, KR
Contact	Jae-Hun Lee
510(k) history	6 submissions · 6 cleared · 2022-2024