FDA 510(k) Premarket Notification

K830483 COONS SOFT STENT

CLEARED

Mar 9, 1983
22 days to decision

K830483 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830483/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Feb 15, 1983
Decision date	Mar 9, 1983
Days to decision	22 days
Third-party review	No

APPLICANT

Company	**Medi-Tech, Inc.**
Location	Mchenry, IL, US
510(k) history	36 submissions · 35 cleared · 1978-1996