FDA 510(k) Premarket Notification

K915719 ANGEION ENDOSCOPIC VALVE SEAL

CLEARED

Feb 18, 1992
60 days to decision

K915719 · Product code: **ODC** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k915719/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Dec 20, 1991
Decision date	Feb 18, 1992
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Angeion Corp.**
Location	Plymouth, MN, US
Contact	STEVEN W HENTLEY
510(k) history	7 submissions · 7 cleared · 1987-1993