FDA 510(k) Premarket Notification

K900016 TRANS/R - FP(3)

CLEARED

Jun 11, 1990
160 days to decision

K900016 · Product code: **FCY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k900016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bulb, Inflation, For Endoscope (FCY)
Date received	Jan 2, 1990
Decision date	Jun 11, 1990
Days to decision	160 days
Third-party review	No

APPLICANT

Company	**CIVCO Medical Instruments Co., Inc.**
Location	Walker, MI, US
Contact	J WEDEL
510(k) history	29 submissions · 29 cleared · 1982-2023