FDA 510(k) Premarket Notification

K880253 BLAKEMORE RETAINER

CLEARED

Mar 11, 1988
51 days to decision

K880253 · Product code: **FEF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k880253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Single Lumen, With Mercury Wt Balloon For Intestinal Intubation And / Or Decompression (FEF)
Date received	Jan 20, 1988
Decision date	Mar 11, 1988
Days to decision	51 days
Third-party review	No

APPLICANT

Company	**Orthopedic Systems, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT R MOORE
510(k) history	95 submissions · 89 cleared · 1977-1996