FDA 510(k) Premarket Notification

K821818 RETRIEVAL BALLOONS

CLEARED

Sep 24, 1982
95 days to decision

K821818 · Product code: **KOD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k821818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Jun 21, 1982
Decision date	Sep 24, 1982
Days to decision	95 days
Third-party review	No

APPLICANT

Company	**American Endoscopy, Inc.**
Location	Mchenry, IL, US
510(k) history	19 submissions · 19 cleared · 1982-1985