FDA 510(k) Premarket Notification

K970994 CORE AND COIL ASSEMBLY GUIDEWIRE

CLEARED

Mar 25, 1997
6 days to decision

K970994 · Product code: **EZB** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k970994/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet For Catheter, Gastro-urology (EZB)
Date received	Mar 19, 1997
Decision date	Mar 25, 1997
Days to decision	6 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lake Region Mfg., Inc.**
Location	Mchenry, IL, US
Contact	KIM AVES
510(k) history	42 submissions · 42 cleared · 1977-2010