FDA 510(k) Premarket Notification

K140482 MANDREL GUIDEWIRE

CLEARED

Apr 8, 2014
41 days to decision

K140482 · Product code: **OCY** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k140482/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Feb 26, 2014
Decision date	Apr 8, 2014
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Lake Region Medical**
Location	Chaska, MN, US
Contact	MATHEW PEXA
510(k) history	16 submissions · 16 cleared · 2008-2026