

K142397 Predicate III GuidewireSep 19, 2014
23 days to decisionK142397 · Product code: **OCY** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k142397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Guidewire, Gastroenterology-urology (OCY)
Date received	Aug 27, 2014
Decision date	Sep 19, 2014
Days to decision	23 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

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