

**K132383 GYRUS ACMI NEPHRO - EZDILATE NEPHROSTOMY
BALLOON DILATION CATHETER**Feb 4, 2014
188 days to decisionK132383 · Product code: **LJE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k132383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Nephrostomy (LJE)
Date received	Jul 31, 2013
Decision date	Feb 4, 2014
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	NEIL KELLY
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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