

K121579 EK DELIVERY DEVICEOct 3, 2012
126 days to decisionK121579 · Product code: **OTZ** · Ophthalmic
Source: <https://www.510kdatabase.net/k121579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Graft Insertion Instrument For Endothelial Keratoplasty (OTZ)
Date received	May 30, 2012
Decision date	Oct 3, 2012
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tdak Medical, Inc.
Location	Irvine, CA, US
Contact	GREG HOLLAND
510(k) history	1 submissions · 1 cleared · 2012-2012

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