

K113574 FLEXITIME MONOPHASE PRO SCANJul 13, 2012
224 days to decisionK113574 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k113574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Dec 2, 2011
Decision date	Jul 13, 2012
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heraeus Kulzer, LLC
Location	South Bend, IN, US
Contact	CHRIS HOLDEN
510(k) history	11 submissions · 11 cleared · 2009-2013

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