

**K101617 FLEXITIME XTREME 2 HEAVY TRAY CARTRIDGE
REFILL, FEXITIME XTREME 2 LIGHT TRAY CARTRIDGE REFILL**Sep 7, 2010
90 days to decisionK101617 · Product code: **ELW** · Dental
Source: <https://www.510kdatabase.net/k101617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Impression (ELW)
Date received	Jun 9, 2010
Decision date	Sep 7, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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