

K143117 Wire Sterilization Package with IndicatorsOct 29, 2015
364 days to decisionK143117 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k143117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Oct 30, 2014
Decision date	Oct 29, 2015
Days to decision	364 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Orthodontics
Location	Sheboygan, WI, US
Contact	TRANG ADAMS
510(k) history	44 submissions · 44 cleared · 1989-2023

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