

K083667 NEEDLE GUIDE FOR 8814, MODEL UA1335, NEEDLE GUIDE FOR 8815, MODEL UA 1336, NEEDLE GUIDE FOR 8824, MODEL UA 1337Feb 2, 2009
53 days to decisionK083667 · Product code: ITX · Radiology
Source: <https://www.510kdatabase.net/k083667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic, Diagnostic (ITX)
Date received	Dec 11, 2008
Decision date	Feb 2, 2009
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	B-K Medical Aps
Location	Herlev, DK
Contact	LARS OKSBY HANSEN
510(k) history	11 submissions · 11 cleared · 2007-2014

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