

K081154 ULTRASOUND SCANNER FLEX FOCUS, MODEL 1202May 23, 2008
30 days to decisionK081154 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k081154/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Apr 23, 2008
Decision date	May 23, 2008
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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