

**K052987 BREAST IMMOBILIZATION AND BIOPSY DEVICE,  
MODELS BI 160-O, BI 160-PA AND BI 160-CC**Nov 8, 2005  
15 days to decisionK052987 · Product code: LNH · Radiology  
Source: <https://www.510kdatabase.net/k052987/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Oct 24, 2005
Decision date	Nov 8, 2005
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Noras Rontgen-Und Medizintechnik GmbH</b>
Location	Denton, TX, US
Contact	CARL ALLETTO
510(k) history	2 submissions · 2 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052987/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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