

K062131 NIO 5MP-M-21 (NIO 5MP MAMMO)

Nov 17, 2006
 114 days to decision

K062131 · Product code: **LLZ** · Radiology
 Source: <https://www.510kdatabase.net/k062131/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 26, 2006
Decision date	Nov 17, 2006
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary
Other names	MDNG-5121 BB

APPLICANT

Company	Barcoviev
Location	Kortrijk, BE
Contact	LIEVEN DE WANDEL
510(k) history	17 submissions · 17 cleared · 2005-2007

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k062131/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026