

**K030363 ORG@NIZER, MODEL VERSION 3.0**Mar 27, 2003  
51 days to decisionK030363 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k030363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 4, 2003
Decision date	Mar 27, 2003
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ebit Sanita, S.P.A.</b>
Location	Indianapolis, IN, US
Contact	COLLEEN DENSMORE
510(k) history	1 submissions · 1 cleared · 2003-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030363/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026