

**K060179 BIO-RAY SDX DIGITAL X-RAY SYSTEM**Feb 8, 2006  
16 days to decisionK060179 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k060179/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Jan 23, 2006
Decision date	Feb 8, 2006
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sigma Biomedics, Inc.</b>
Location	Prospect Heights, IL, US
Contact	KIM ANTOL
510(k) history	1 submissions · 1 cleared · 2006-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k060179/> 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 18, 2026