

**K963408 VISUALINE D HCG**Oct 18, 1996  
50 days to decisionK963408 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k963408/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 29, 1996
Decision date	Oct 18, 1996
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sun Biomedical Laboratories, Inc.</b>
Location	Cherry Hill, NJ, US
Contact	MING SUN, PH.D.
510(k) history	17 submissions · 17 cleared · 1994-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963408/> 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 June 28, 2026