

**K003795 BIOLUCENT MAMMOGRAPHY CUSHION**Feb 14, 2001  
68 days to decisionK003795 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k003795/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mammographic (IZH)
Date received	Dec 8, 2000
Decision date	Feb 14, 2001
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolucent, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	STEVE GEX
510(k) history	6 submissions · 5 cleared · 2001-2007

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