

**K080565 MODIFICATION TO: SAVI APPLICATOR KIT**Apr 4, 2008  
35 days to decisionK080565 · Product code: **JAQ** · Radiology  
Source: <https://www.510kdatabase.net/k080565/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Feb 29, 2008
Decision date	Apr 4, 2008
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cianna Medical, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	GARY MOCNIK
510(k) history	8 submissions · 6 cleared · 2008-2018

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080565/> 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 16, 2026