

**K143537 Sirius Starmobile tiara**Mar 6, 2015  
81 days to decisionK143537 · Product code: **IZL** · Radiology  
Source: <https://www.510kdatabase.net/k143537/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Mobile (IZL)
Date received	Dec 15, 2014
Decision date	Mar 6, 2015
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Hitachi Medical Systems America, Inc.</b>
Location	Twinsburg, OH, US
Contact	DOUG THISTLEWAITE
510(k) history	100 submissions · 100 cleared · 1991-2017

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143537/> 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