

**K182079 Solstice SRS Immobilization System**Sep 7, 2018  
36 days to decisionK182079 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k182079/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Aug 2, 2018
Decision date	Sep 7, 2018
Days to decision	36 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Solstat Immobilization System; Solstice Thermoplastic Mask

**APPLICANT**

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Company	<b>Medtec Inc. Db a Civco Medical Solutions</b>
Location	Orange City, IA, US
Contact	Alena Newgren
510(k) history	2 submissions · 2 cleared · 2012-2018

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Mark Job

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182079/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 26, 2026