

**K011991 MODIFICATION TO MEDRAD SPECTRIS MR  
INJECTOR**Aug 21, 2001  
56 days to decisionK011991 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011991/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Jun 26, 2001
Decision date	Aug 21, 2001
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Medrad, Inc.</b>
Location	Mchenry, IL, US
Contact	LORRAINE R FREDES
Website	<a href="http://www.medrad.com/">http://www.medrad.com/</a>
510(k) history	105 submissions · 105 cleared · 1976-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011991/> 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 17, 2026