

**K833645 CONTRAST MEDIA INJECT. SET CMS**Apr 17, 1984  
183 days to decisionK833645 · Product code: **DXT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k833645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Injector And Syringe, Angiographic (DXT)
Date received	Oct 17, 1983
Decision date	Apr 17, 1984
Days to decision	183 days
Third-party review	No

**APPLICANT**

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Company	<b>Gish Biomedical, Inc.</b>
Location	Mchenry, IL, US
510(k) history	75 submissions · 75 cleared · 1983-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k833645/> 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 26, 2026