

**K980282 URESIL DILATOR WITH RADIOPAQUE MARKER**Apr 24, 1998  
88 days to decisionK980282 · Product code: **DRE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k980282/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Vessel, For Percutaneous Catheterization (DRE)
Date received	Jan 26, 1998
Decision date	Apr 24, 1998
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Uresil Corp.</b>
Location	Mchenry, IL, US
Contact	LEV MELINYSHYN
510(k) history	45 submissions · 44 cleared · 1981-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980282/> 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 22, 2026