

**K143447 Dilapan-S**Apr 17, 2015  
136 days to decisionK143447 · Product code: **PKN** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k143447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dilator, Cervical, Synthetic, Osmotic (PKN)
Date received	Dec 2, 2014
Decision date	Apr 17, 2015
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medicem Technology S.R.O</b>
Location	Kamenne Zehrovice, CZ
Contact	Adam Vlcek
510(k) history	1 submissions · 1 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143447/> 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 June 4, 2026