

**K011395 MEDTRONIC COLVIN-GALLOWAY FUTURE  
ANNULOPLASTY BAND, MODEL 638B**Jul 12, 2001  
66 days to decisionK011395 · Product code: **KRH** · Cardiovascular  
Source: <https://www.510kdatabase.net/k011395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ring, Annuloplasty (KRH)
Date received	May 7, 2001
Decision date	Jul 12, 2001
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Vascular</b>
Location	Walker, MI, US
Contact	CHARLES DOWD
510(k) history	475 submissions · 453 cleared · 1977-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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