

**K163055 Reprocessed Kendall SCD Express Foot Cuff**Dec 23, 2016  
52 days to decisionK163055 · Product code: **JOW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163055/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sleeve, Limb, Compressible (JOW)
Date received	Nov 1, 2016
Decision date	Dec 23, 2016
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien</b>
Location	North Haven, CT, US
Contact	Jennifer Sullivan
510(k) history	130 submissions · 126 cleared · 2008-2024

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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