

**K123771 KYPHON EXPRESS II INFLATABLE BONE TAMPS**Dec 21, 2012  
14 days to decisionK123771 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k123771/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Arthroscope (HRX)
Date received	Dec 7, 2012
Decision date	Dec 21, 2012
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic</b>
Location	Minneapolis, MN, US
Contact	HETAL JAWAHAR THAKKER
Website	<a href="http://www.medtronic.com/us-en/index.html">http://www.medtronic.com/us-en/index.html</a>
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...

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