

**K161470 Internal Distraction - Sterile**Dec 1, 2016  
188 days to decisionK161470 · Product code: **MQN** · Dental  
Source: <https://www.510kdatabase.net/k161470/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	May 27, 2016
Decision date	Dec 1, 2016
Days to decision	188 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>KLS-Martin L.P.</b>
Location	Jacksonville, FL, US
Contact	JENNIFER DAMATO
Website	<a href="https://www.klsmartin.com">https://www.klsmartin.com</a>
510(k) history	78 submissions · 78 cleared · 1994-2026

KLS-Martin L.P. is a surgical device manufacturer based in Jacksonville, US. The company specializes in surgical innovation across orthopedic, dental, and neurology device categories. KLS-Martin has received FDA 510(k) clearances from total submissions since its first clearance in 1994. The company maintains active regulatory status, with its latest FDA 510(k) clearance in 2026. Core product areas include orthopedic implants and fixation systems, dental implants and surgical instruments, and neurosurgical devices including cranial implants and expansion systems. Notable r...

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