

K034027 KLS MARTIN 3DX EXTERNAL DISTRACTION SYSTEMFeb 27, 2004
60 days to decisionK034027 · Product code: **MQN** · Dental
Source: <https://www.510kdatabase.net/k034027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	External Mandibular Fixator And/or Distractor (MQN)
Date received	Dec 29, 2003
Decision date	Feb 27, 2004
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	KLS-Martin L.P.
Location	Jacksonville, FL, US
Contact	JENNIFER DAMATO
Website	https://www.klsmartin.com
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...
