FDA 510(k) Premarket Notification

# K972047 KLS-MARTIN RIGID EXTERNAL DISTRACTION DEVICE

**CLEARED**

Jun 24, 1997
22 days to decision

K972047 · Product code: **MQN** · Dental
Source: https://www.510kdatabase.net/k972047/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | External Mandibular Fixator And/or Distractor (MQN) |
| Date received | Jun 2, 1997 |
| Decision date | Jun 24, 1997 |
| Days to decision | 22 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **KLS-Martin L.P.** |
| Location | Jacksonville, FL, US |
| Contact | ED RANSOM |
| 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...