FDA 510(k) Premarket Notification

K921823 ARTHREX ARTHROSCOPY ICE BLADE

CLEARED

Oct 15, 1992
182 days to decision

K921823 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k921823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 16, 1992
Decision date	Oct 15, 1992
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Arthrex, Inc.**
Location	Naples, FL, US
Contact	DON GRAFTON
Website	https://www.arthrex.com
510(k) history	346 submissions · 342 cleared · 1992-2026

Arthrex, Inc. is a medical device manufacturer based in Naples, US. The company specializes in surgical implants and instruments for orthopedic procedures. Arthrex has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. Recent cleared devices include suture anchors, plating systems, nails, and specialized fixation devices for shoulder, ankle, and lower extremity procedures. The latest FDA 510(k) clearance was received in 2026,...