

K963304 STRYKER TEMPEST ORTHOPEDIC PUMPJan 22, 1997
153 days to decisionK963304 · Product code: **HRX** · Orthopedic
Source: <https://www.510kdatabase.net/k963304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Aug 22, 1996
Decision date	Jan 22, 1997
Days to decision	153 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Endoscopy
Location	San Jose, CA, US
Contact	ROY S CHIN
Website	https://www.stryker.com
510(k) history	99 submissions · 99 cleared · 1993-2026

Stryker Endoscopy is a medical device manufacturer based in San Jose, US. The company specializes in endoscopic and surgical imaging systems for minimally invasive procedures. Stryker Endoscopy has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with its latest clearance in 2026. Its portfolio spans General & Plastic Surgery devices, orthopedic surgical tools, and obstetric and gynecologic instruments. Recent cleared devices include advanced imaging systems such as 4K camera platforms...
