FDA 510(k) Premarket Notification

K970284 ARTOS, DIPLOS SYSTEM

CLEARED

Apr 21, 1997
87 days to decision

K970284 · Product code: **KWY** · Orthopedic
Source: https://www.510kdatabase.net/k970284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY)
Date received	Jan 24, 1997
Decision date	Apr 21, 1997
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Turnkey Intergration USA, Inc.**
Location	Indianapolis, IN, US
510(k) history	26 submissions · 23 cleared · 1990-1999