FDA 510(k) Premarket Notification

K020683 ISOROD PD-103 IMPLANT, MODEL ATI-PD-103

CLEARED

Dec 17, 2002
288 days to decision

K020683 · Product code: **KXK** · Radiology
Source: https://www.510kdatabase.net/k020683/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source, Brachytherapy, Radionuclide (KXK)
Date received	Mar 4, 2002
Decision date	Dec 17, 2002
Days to decision	288 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ati Medical, Inc.**
Location	Las Vegas, NV, US
Contact	MICHAEL WIENHOLT
510(k) history	2 submissions · 2 cleared · 1991-2002