FDA 510(k) Premarket Notification

K031273 AMERITEK SURE-POINT HDR NEEDLE TEMPLATE

CLEARED

Jul 15, 2003
84 days to decision

K031273 · Product code: **JAQ** · Radiology
Source: https://www.510kdatabase.net/k031273/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Applicator, Radionuclide, Remote-controlled (JAQ)
Date received	Apr 22, 2003
Decision date	Jul 15, 2003
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Amertek Medical, Inc.**
Location	Singer Island, FL, US
Contact	GREG WIITA
510(k) history	3 submissions · 3 cleared · 2001-2003

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k031273/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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