K093637 JMS BLUNT A. V. FISTULA NEEDLE SET WITH SITE PREPARATION TOOL MODEL 820-5300, 820-6300 AND 820-7300

CLEARED

Feb 9, 2010
77 days to decision

K093637 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k093637/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Nov 24, 2009
Decision date	Feb 9, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Jms North America Corp.**
Location	Hayward, CA, US
Contact	E J SMITH
510(k) history	10 submissions · 10 cleared · 2003-2010