FDA 510(k) Premarket Notification

CLEARED

K993411 FEMISCAN CLINIC SYSTEM, MODEL FS-ICTRA AND FEMISCAN PERSONAL SYSTEM, MODEL FS-HMTR

Jan 10, 2000
90 days to decision

K993411 · Product code: **HIR** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k993411/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Perineometer (HIR)
Date received	Oct 12, 1999
Decision date	Jan 10, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Mega Electronics , Ltd.**
Location	The Hague, NL
Contact	DAVID MAHONEY
510(k) history	4 submissions · 4 cleared · 1997-2015