FDA 510(k) Premarket Notification

K103022 KIM

CLEARED

Dec 20, 2011
434 days to decision

K103022 · Product code: **OTN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k103022/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Oct 12, 2010
Decision date	Dec 20, 2011
Days to decision	434 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neomedic International S.L.**
Location	Minneapolis, MN, US
Contact	JEFFREY R SHIDEMAN
510(k) history	2 submissions · 2 cleared · 2011-2012