K171505 Dimesol Disposable AV Fistula Needle Set (Non-Safety Series) and Dimesol Disposable AV Fistula Needle Set (Safety Series)

CLEARED

May 17, 2018
359 days to decision

K171505 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k171505/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	May 23, 2017
Decision date	May 17, 2018
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dimesol, Inc.**
Location	Lewisberry, PA, US
Contact	Stephen P. Callaghan
510(k) history	2 submissions · 2 cleared · 2018-2018