

K152951 Advanced Imaging Modality (AIM) Sterilization Tray, Endoscope and Camera Sterilization Tray, Camera Sterilization Tray

Dec 28, 2015
83 days to decision

K152951 · Product code: **KCT** · General Hospital
Source: <https://www.510kdatabase.net/k152951/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Oct 6, 2015
Decision date	Dec 28, 2015
Days to decision	83 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Paragon Medical, Inc.
Location	Fort Wayne, IN, US
Contact	MIKE GOSMEYER
510(k) history	2 submissions · 2 cleared · 2003-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k152951/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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