

DATE: 18 Jun 2021

SUBJECT: FDA Documentation – Palliare

Establishment Registration: Palliare
Palliare, Galway Business Park
Dangan
Galway, IE H91P2DK

Establishment Registration Number: 3017590240

Owner/Operator Number: 10078788

Official Correspondent: John O’Dea
Telephone: + 353-91-516362
E-mail: jodea@palliare.com

US Agent: Paul Dryden
ProMedic, LLC
President
Telephone: 239-307-6061
E-mail: paul.dryden@promedic.cc

Initial Importer: Palliare, Inc.
301 Mission Ave #211
Oceanside, CA 92054
Contact Name: Janet MacGregor
Telephone: 760-696-3243
E-mail: jmacgregor@palliare.com

Establishment Registration Number: 3017565103

Owner/Operator Number: 10078788

EIN: 30-1252942

<u>General Devices:</u>	<u>Description and use:</u>
Laparoscopic insufflator	The EVA15 insufflator is intended for use in diagnostic and/or therapeutic endoscopic and laparoscopic procedures to distend a cavity by filling it with gas and to evacuate surgical smoke.
Adaptor, Bulbs, Miscellaneous, For Endoscope	EndoTrap™ is used in conjunction with an anesthesia mask and bacterial filter to reduce the risk of aerosolized particles caused by an endoscopic procedure entering the room.

Part#	Description	DEV / DFE	LST	DII	PMN
EVA15	Laparoscopic insufflator	10078788	D424778	10078788	K202799
EndoTrap	Adaptor, Bulbs, Miscellaneous, For Endoscope	10078788	D425019	10078788	N/A

Device Listing Information:

Number: D424778
Device Class: II
510(k): K202799
Product Code: 78 H - - IF
Regulation Number: 21 CFR 884.1730
Classification Name: Insufflator, Laparoscopic
Intended Use Code: 081.001

Device Listing Information:

Number: D425019
Device Class: 1
510(k): 510(k) Exempt
Product Code: 78 F - - FY
Regulation Number: 21 CFR 876.1500
Classification Name: Adaptor, Bulbs, Miscellaneous, For Endoscope
Intended Use Code: 081.001

Definitions:

DEV Device Foreign Manufacturer or
DFE Device Foreign Exporter
LST Device Listing
DII Device Initial Importer
PMN 510(k) number