DATE: 9 June 2023

SUBJECT: FDA Documentation – Palliare

Establishment Registration:	Palliare Palliare, Galway Business Park Dangan Galway, IE H91P2DK
Establishment Registration Number:	3017590240
Owner/Operator Number:	10078788
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Establishment Registration Number:	3017565103
Owner/Operator Number:	10078788
EIN:	30-1252942

General Devices:	**Description and use:**
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.
Endoscopic Insufflator	The EVA5 Insufflator is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend the gastrointestinal tract by filling it with gas.

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
EVA5	Endoscopic Insufflator	10078788	D505552	10078788	K230474
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:	D505552
Device Class:	II
510(k):	K230474
Product Code:	78 F - - CX
Regulation Number:	21 CFR 876.1500
Classification Name:	Insufflator, Automatic carbon-dioxide for endoscope
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