

Medical Device Details

Sponsor:	Mango Medtech Limited 12 Madden Street Auckland New Zealand
WAND Reference:	210831-WAND-6XHWXC
Sponsors Own Reference:	Endoluxe eVS Endoscopic Visualization System
GMDN:	Endoscope video camera [35958]
Class:	I
Intended Purpose:	Wireless battery-operated digital camera with light source intended for use as an illuminating, imaging and image data acquisition system during endoscopic procedures, and used in conjunction with a fiber optic endoscope. AVG Advanced Technologies 4140 Utica Ridge Road Bettendorf Iowa United States
Manufacturer:	
ARTG ID:	<ul style="list-style-type: none"> > The device is supplied unsterilised. > The device is not intended to be invasive. > The device is not intended for single use. > The device is an active device. > The device does not contain material or ingredients of microbial origin. > The device does not contain material or ingredients of recombinant origin. > The device does not contain material or ingredients manufactured or formulated using a genetically modified organism. > The device does not contain material or ingredients of human origin. > The device does not contain human blood or its components. ☐ > The device consists of: System <ul style="list-style-type: none"> ☐ Components: <ul style="list-style-type: none"> > Component: Endoluxe eVS Charger, Endoluxe eVS Orb charging and storage. > Component: Endoluxe eVS HDMI Cable, Connecting receiver to video display monitor. > Component: Endoluxe eVS Light Adaptor, Adaptor accommodating various light port and endoscope configurations. > Component: Endoluxe eVS Mouse, Used for navigation of connected display menu. > Component: Endoluxe eVS Orb, 32269 Camera, television, endoscopic, without audio • 35906 Endoscopic light source, battery-powered > Component: Endoluxe eVS Power Adaptor, Designed to charge Endoluxe eVS Orb. > Component: Endoluxe eVS Receiver, 18034 Endoscopic video image processor > The device does not contain material or ingredients of animal origin. > The device is not medicated. > The device is not formulated. > The product does not contain a medicine that has consent for marketing in New Zealand. > The product does not contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device.
Status:	Active