Establishment Registration & Device Listing

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Proprietary Name:	EndoGrab, EndoLift
Classification Name:	RETRACTOR
Product Code:	GAD
Device Class:	1
Regulation Number:	878.4800
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	VIRTUAL PORTS LTD
Registered Establishment Number:	3006169466
Owner/Operator:	VIRTUAL PORTS LTD
Owner/Operator Number:	9095859
Establishment Operations:	Manufacturer

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/www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfPCD/classification.cfm?ID=5499

Product Classification

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Device	Retractor
Regulation Description	Manual surgical instrument for general use.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General & Plastic Surgery
Product Code	GAD
Premarket Review	Office of Device Evaluation (ODE) Division of Surgical Devices (DSD) General Surgery Devices Branch Two - Surgical (GSDB2)
Submission Type	510(K) Exempt
Regulation Number	878.4800
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

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