ViriMASK™ FDA Registration

OHK MEDICAL DEVICES LTD ISRAEL		3003889520	2020
• Tourniquet, Nonpneumatic - HemaClear Sterile Surgical Tourniquet; HemaShock, Medical Apparatus For Use In Emergency Medicine Procedures.			Manufacturer
• Brush, Scrub, Operating-Room - CleaRoller, Tool For Spreading Disinfectant Solutions Evenly, When Preparing Surgical Fields			Manufacturer
• Respirator, Surgical - ViriMask			Manufacturer

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Device	Respirator, Surgical
Regulation Description	Surgical apparel.
Definition	A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures subject to 21 CFR 878.9 and the conditions for exemption identified in 21 CFR 878.4040(b)(1).
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General Hospital
Product Code	MSH
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(K) Exempt
Regulation Number	878.4040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of class II (special controls) devices subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.

Recognized Consensus Standards

- 3-129 AAMI ANSI EC53:2013
  ECG trunk cables and patient leadwires
- 6-254 ASTM F2100-11 (Reapproved 2018)
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-335 ASTM F2101-14
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- 6-406 ASTM F1862/F1862M-17
  Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- 6-425 ASTM F2100-19
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-427 ASTM F2101-19
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

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