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Establishment Registration & Device Listing

1 result found for Establishment Registration or Business Trade Name: health-Mor

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Establishment Name	+	Registration Number	Current Registration Yr
Health-Mor, Inc	OH/USA	3003007759	2021
Cleaner, Air, Medical Recirculating - DEFENDER			Manufacturer

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Product Classification

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Device Cleaner, Air, Medical Recirculating Regulation Description Medical recirculating air cleaner.

Regulation Medical Specialty General Hospital **Review Panel** General Hospital

Product Code

Premarket Review Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)

Submission Type 510(k) **Regulation Number** 880.5045 Device Class 2

Total Product Life Cycle (TPLC) TPLC Product Code Report

GMP Exempt? **Summary Malfunction** Eligible Reporting Implanted Device? No Life-Sustain/Support Device? No

Third Party Review

Eligible for <u>Accredited Persons Program</u>

Accredited Persons

- Accelerated Device Approval Services
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

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