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510(k) Premarket Notification



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Device Classification Name	Cleaner, Air, Medical Recirculating ²²
510(K) Number	K010616
Device Name	DEFENDER ROOM AIR CLEANER, MODEL RAC-4000A
Applicant	HMI INDUSTRIES, INC. 13325 DARICE PKWY. Strongville, OH 44149
Applicant Contact	Jacqueline Percell
Correspondent	HMI INDUSTRIES, INC. 13325 DARICE PKWY. Strongville, OH 44149
Correspondent Contact	Jacqueline Percell
Regulation Number	880.5045 ²³
Classification Product Code	FRF ²⁴
Date Received	03/01/2001
Decision Date	03/28/2001
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Type	Special
Reviewed By Third Party	No
Combination Product	No

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