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510(k) Premarket Notification



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Device Classification Name	Bougie, Esophageal, Ent ²²
510(K) Number	K844169
Device Name	VOLUMATIC
Applicant	GLAXO, INC. 5 MOORE DR. P.O. BOX 13358 Research Triangle, NC 27709
Applicant Contact	David Macfarlane
Correspondent	GLAXO, INC. 5 MOORE DR. P.O. BOX 13358 Research Triangle, NC 27709
Correspondent Contact	David Macfarlane
Regulation Number	874.4420 ²³
Classification Product Code	KCD ²⁴
Date Received	10/25/1984
Decision Date	11/09/1984
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Ear Nose & Throat
510k Review Panel	Ear Nose & Throat
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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