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510(k) Premarket Notification



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Device Classification Name	Lamp, Infrared, Therapeutic Heating ²²
510(k) Number	K053376
Device Name	CHUNG CHENG FAR INFRARED RAY HEALTHFUL LAMP (OR MEDICAL FIR RADIATOR), MODEL CH-8810
Applicant	Chung Cheng Electric Heating Co., Ltd. 2904 N. Boldt Dr. Flagstaff, AZ 86001
Applicant Contact Correspondent	JENNIFER REICH Chung Cheng Electric Heating Co., Ltd. 2904 N. Boldt Dr. Flagstaff, AZ 86001
Correspondent Contact	JENNIFER REICH
Regulation Number	890.5500 ²³
Classification Product Code	ILY ²⁴
Date Received	12/05/2005
Decision Date	02/16/2006
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Physical Medicine
510k Review Panel	Physical Medicine
Summary	Summary ²⁵
Type	Traditional
Reviewed by Third Party	No
Combination Product	No
Predetermined Change Control Plan Authorized	No