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510(k) Premarket Notification Database

Device Classification Name	Lamp, Infrared
510(K) Number	K931261
Regulation Number	890.5500
Device Name	SPECTROPAD SYSTEM SMI
Applicant	11111 D West 8th Ave. Lakewood, CO 80215
Contact	Joe Markham
Product Code	ILY
Date Received	03/12/1993
Decision Date	03/31/1994
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Physical Medicine
Statement/Summary/Purged Status	Statement/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No

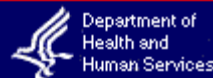
Database Updated 1/05/2005

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[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2004]
[CITE: 21CFR890.5500]



TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

[PART 890 -- PHYSICAL MEDICINE DEVICES](#)

Subpart F -- Physical Medicine Therapeutic Devices

Sec. 890.5500 Infrared lamp.

(a) *Identification.* An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

(b) *Classification.* Class II (performance standards).

Database Updated April 1, 2004

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