



INTERNATIONAL SPECIALTY PRODUCTS

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Advisory note:

The GAFCHROMIC[®] EBT film based dosimetry system is a quality assurance device intended for use as an accessory to a medical charged-particle radiation therapy system. As such, this film dosimetry system is consistent with the requirement of 21 CFR Section 892.5050 for classification as a Class 2 medical device; exempt from pre-market notification procedures.

The GAFCHROMIC[®] EBT film based dosimetry system consists of the following components:

- a) GAFCHROMIC[®] EBT dosimetry film;
- b) A single 1- year renewable license or one unlimited license of FilmQA[™] - an IMRT treatment plan verification software;
- c) Epson Expression 1680 Professional Color Film Scanner with Transparency Adapter

Reference:

[Title 21, Volume 8]
[Revised as of April 1, 2005]
[CITE: 21 CFR Section 892.5050]

PART 892 -- RADIOLOGY DEVICES

Subpart F--Therapeutic Devices

Sec. 892.5050 Medical charged-particle radiation therapy system.

Link:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm?db=PCD&id=MWW>

