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Establishment Registration & Device Listing



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10031317

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Establishment Name		Registration Number	Current Registration Yr
RICHWAY & FUJI BIO INC.	HI/USA	3002743035	2015
<ul style="list-style-type: none"> • Pad, Heating, Powered - Amethyst & Tourmaline Mini Biomat; Amethyst & Tourmaline Pillow; Amethyst King Biomat; Amethyst Massage Table (Professional) Biomat; Amethyst Queen Biomat; Amethyst Single Biomat; Biomat; Jade Powder Single Biomat; Tourmaline & Jade Queen Biomat 			Specification Developer; Complaint File Establishment

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Establishment:

RICHWAY & FUJI BIO INC.
1314 S King St Suite 520
Honolulu , HI 96814

Registration Number: 3002743035

Status: Active

Initial Distributor/Importer: Yes

*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.

Date Of Registration Status: 2015

Owner/Operator:

[Richway & Fuji Bio Inc.](#)
1314 South King Street, Suite 520
Hon, HI 96814

Owner/Operator Number: [10031317](#)

Official Correspondent:

Janelle Hirano
Richway & Fuji Bio Inc.
1314 South King Street Suite 520
Honolulu, HI 96814

Phone: 808-5892800



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Establishment Registration & Device Listing



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Proprietary Name:	Amethyst & Tourmaline Mini Biomat; Amethyst & Tourmaline Pillow; Amethyst King Biomat; Amethyst Massage Table (Professional) Biomat; Amethyst Queen Biomat; Amethyst Single Biomat; Biomat; Jade Powder Single Biomat; Tourmaline & Jade Queen Biomat
Classification Name:	PAD, HEATING, POWERED
Product Code:	IRT
Device Class:	2
Regulation Number:	890.5740
Medical Specialty:	Physical Medicine
Registered Establishment Name:	RICHWAY & FUJI BIO INC.
Registered Establishment Number:	3002743035
Owner/Operator:	Richway & Fuji Bio Inc.
Owner/Operator Number:	10031317
Establishment Operations:	Specification Developer; Complaint File Establishment



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Product Classification

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Device	Pad, Heating, Powered
Regulation Description	Powered heating pad.
Regulation Medical Specialty	Physical Medicine
Review Panel	Physical Medicine
Product Code	IRT
Premarket Review	Office of Device Evaluation (ODE) Division of Neurological and Physical Medicine Devices (DNPMD) Physical Medicine and Neurotherapeutic Devices Branch (PNDB)
Submission Type	510(K) Exempt
Regulation Number	890.5740
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
<p>Note: Class II devices the Food and Drug Administration (FDA) has also published a list of Class II (special controls) devices subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the Modernization Act.</p>	
<p>Guidance Document</p> <ul style="list-style-type: none"> ● Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Heating and Cooling Devices 	
Third Party Review	Not Third Party Eligible



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CFR - Code of Federal Regulations Title 21

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[Code of Federal Regulations]
 [Title 21, Volume 8]
 [Revised as of April 1, 2014]
 [CITE: 21CFR890.5740]



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. 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E part 807 of this chapter subject to 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 63 FR 59231, Nov. 3, 1998]