

Health Sciences Authority
11 Biopolis Way #11-01 Helios
Singapore 138667
Tel: 65 6866 3400 Fax: 65 6478 9076
Website: www.hsa.gov.sg



17/10/2013

Ganesh Geetha

REHAB ASIA PTE. LTD.
11 KALLANG PLACE, #07-11, SINGAPORE 339155

Dear Sir/Mdm,

Please refer to your Pre-Market Application submitted on 22/02/2012.
Job Reference No.: MD12545529X
Device Name(s): <Please refer to attached Schedule>

The Health Sciences Authority has completed the review of this application, and we are pleased to inform you that the information provided has been adequate to demonstrate the quality, safety, and performance of the product for use. The application is approved effective from the date of this letter and approved indication(s) can be found in the schedule attached.

The registrant is reminded that, notwithstanding the registration of a medical device under the Health Products Act, the supply and use of any medical device in Singapore should also comply with the requirements under other applicable legislations (e.g. Private Hospitals and Medical Clinics Act, Professional Acts*, Radiation Protection Act).

**Professional Acts include Medical Registration Act, Dental Registration Act and others.*

Please contact Amritamayee Sahoo, Regulatory Specialist, at Tel: 6866 3546 or E-mail: Amritamayee_SAHOO@hsa.gov.sg should you need further clarification.

Yours sincerely,
Wong Woei Jiuang (Ms)

A handwritten signature in black ink, appearing to read 'Wong Woei Jiuang', with a horizontal line underneath.

Director, Medical Device Branch
for Group Director
Health Products Regulation Group

1/2



THE SCHEDULE

No.	Device Proprietary/Brand Name	Intended Use
1	RESTORATIVE THERAPIES RT600 FES STEPPER ERGOMETER	Intended for general rehabilitation for : Relaxation of muscle spasms; Prevention or retardation of disuse atrophy; Increasing local blood circulation; Maintaining or increasing range of motion
2	RESTORATIVE THERAPIES RT300 FUNCTIONAL ELECTRICAL STIMULATION CYCLE ERGOMETER	Intended for general rehabilitation for :Relaxation of muscle spasms;Prevention or retardation of disuse atrophy; Increasing local blood circulation; Maintaining or increasing range of motion
3	RESTORATIVE THERAPIES RT200 FUNCTIONAL ELECTRICAL STIMULATION RECUMBENT ELLIPTICAL ERGOMETER	Intended for general rehabilitation for :Relaxation of muscle spasms;Prevention or retardation of disuse atrophy; Increasing local blood circulation; Maintaining or increasing range of motion

END OF PRODUCT LIST