

Fiscal Year 2023 USA FDA **CERTIFICATION OF REGISTRATION**

This certifies that:

Shanghai Huifeng Medical Instrument Co., Ltd.

Building 2, No. 885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, 201311, China

has completed the FDA Establishment Registration (as manufacturer, contract manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through MicroKy Services, LLC.

Registration Number: 3008610343 Owner/Operator Number: 10048425

Device Listings:

Listing Product Number

Device Name

> Proprietary Name

Code **FWX**

TABLE, OPERATING-ROOM, MECHANICAL

Manual Hydraulic Operating Table: MT600, HFMH3008A, HFMH3008D, HFMH3008AB, HFMS3001B, HFMH700A, HFMH700AB, HFMPB06A, HFMPB06B, HFMPB06C, HFOOT99,

HF201A, HF201C, HF201B, HF201D, HF202A, HF202B

D468315 GDC

D468314

TABLE, OPERATING-ROOM, ELECTRICAL

➤ Electric Operating Table: HFEOT99C, HFEOT99X, HFEOT99, HFEOT2000, HFEOT99D, HFEOT99S, HFEOT100, HFEPB99B, HFEPB99D, HFOOT99A, HFOOT99A-1, HF-2000J, HFEOT2000E. HFEPB99A, HF203A, HF203H, HF203F, HF203O, HF203D. HF203M, HF203E, HF203I, HF204-1G, HF204-1R, HF204-1B, HF204-1D, HF204-8, HF204-Q, HF205-7A, HF205-7, HF205-1A, HF205-1B, HF205-2A, HF205-2B, HF205-12E, HF205-12D,

HF205-3A, HF204-A

D468488 HST

APPARATUS, TRACTION, NON-POWERED

510(k) Exempt

Premarket

Submission Type

510(k) Exempt

510(k) Exempt

> Orthopaedics Traction Frame: 1005, 1006, 1007

MicroKy Sevices, LLC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MicroKy Services, LLC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MicroKy Services, LLC assumes no liability to any person or entity in connection with the foregoing. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, MicroKy Services, LLC is not affiliated with the U.S. Food and Drug Administration.



Executive Director Issued: Oct. 28, 2022 Cert. No.: 2022102802

Expiration Date: Dec. 31, 2023