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SEP 27 2005

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Jul 16, 2005

1. Company and Correspondent making the submission:

Name – Saehan Corp.

Address – 973, Yangdeok-Dong, Masan-City, Kyungsangnam-Do, Korea

Telephone – +82-55-294-0381

Fax – +82-55-293-5019

Contact – Mrs. Tae Sun, Byun / Manager

Internet – saehancorp@korea.com

2. Device :

Trade/proprietary name : SH5003 Digital Hand Dynamometer
SH5006 Digital Pinch Gauge

Common Name : DC-powered dynamometer

Classification Name : DC-powered dynamometer

3. Predicate Devices :

Manufacturer : Ametek, Inc.

Device : Dynamometer(FCE Series)

510(k) Number : K042889(Decision Date–Nov. 16. 2004)

4. Classifications Names & Citations :

21CFR 888.1240, LBB, DC-powered dynamometer, Class2

5. Description :

5.1 Digital Hand Dynamometer(SH5003)

In health care environment, accurate and objective data is required for reimbursable rehabilitation services, making the SAEHAN Digital Hand Dynamometer an

indispensable tool.

Ideal for routine screening of grip strength and initial and ongoing evaluation of clients with hand trauma and dysfunction.

Virtually leak-proof hydraulics and isometric design ensure accurate, reproducible results and years of reliable service.

Built to last, a shock-resistant rubber cap protects the stainless steel gauge and a wrist strap prevent s accidental damage if dropped.

The SAEHAN Digital Hand Dynamometer combines Precision with convenient features:

-Dual-scale readout displays isometric grip force from 0-300 lbs.(0-136 Kg)

-Peak-hold needle automatically retains the highest reading until reset.

-Handle easily adjusts to five grip position, from 1 3/8" –3 3/8", in half-inch increments.

5.2 Digital Pinch Gauge(SH5006)

Unlike conventional pinch gauges, The SAEHAN Digital Pinch Gauge's unique design frees the client to perform a true pinch pattern because the therapist, not the client, supports he weight of the gauge.

A highly accurate pinch-force measurement, devoid of artifact, is the result. Red indicator needle remains at maximum reading until reset.

Measures pinch force to 60lbs. includes instructions, handy carrying case.

6. Indication for use :

The SH5003 & SH5006 Digital Hand Dynamometer & Digital Pinch Gauge are for performing manual muscle testing to measure grip or pinch strength in an injured and uninjured.

7. Comparison with predicate device :

Saehan Corp. believes that the SH5003 & SH5006 Digital Hand Dynamometer & Digital Pinch Gauge is substantially equivalent to Dynamometer(FCE Series) of Ametek, Inc..

8. Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1(1990) was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Saehan Corp. concludes that the SH5003 & SH5006 Digital Hand Dynamometer & Digital Pinch Gauge is safe and effective and substantially equivalent to predicate devices as described herein.

10. Saehan Corp. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Sachan Corporation
c/o Mr. Charlie Mack, PE
Prinicipal Engineer
International Regulatory Consultants
340 Shady Grove Road
Flintville, Tennessee 37335

Re: K052309
Trade/Device Name: SH5003 Digital Hand Dynamometer & SH5006 Digital Pinch Gauge
Regulation Number: 21 CFR 888.1240
Regulation Name: AC-powered dynamometer
Regulatory Class: II
Product Code: LBB
Dated: August 20, 2005
Received: August 24, 2005

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

not a consultant for the 510(k) submitter]

Indications for Use

510(k) Number(if known):

Device Name: SH5003 Digital Hand Dynamometer & SH5006 Digital Pinch Gauge

Indications for Use:

The SH5003 & SH5006 Digital Hand Dynamometer & Digital Pinch Gauge are for performing manual muscle testing to measure grip or pinch strength in an injured and uninjured.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K052309