FEB 14 2006

K060042

Besteam Technology Inc.

No.16-1, Ziqiang 1st Rd., Zhongli City, Taoyuan Hsien, Taiwan

Phone: +886-3-4345111 Fax: +886-3-4342572

510(k) Summary

Device

Trade name: **LANDLEX P100X**

Common (generic) name: **Electrical scooter**

Classification name: **Motorized three-wheeled vehicle**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3800**

Product Code: **INI**

Classification: **Class II**

Predicate devices

LANDLEX S300X (K050792) / Besteam Technology Inc.

Proasia L3402 (K052378) / Proasia

Intend use of device

LANDLEX P100X scooter is intended for an indoor/outdoor scooter that provides transportation for disabled or elderly persons limited to a seated position.

Device description:

The **LANDLEX P100X** scooter is an indoor/outdoor transportation vehicles which is battery operated. The movement of the scooter is controlled by a tiller handle and a **thumb operated potentiometer throttle control lever** to engage and disengage the scooter motion in both the forward and reverse directions.

Substantial equivalence:

The **LANDLEX P100X scooter** is substantially equivalent to the **LANDLEX S300X (K050792)** and **Proasia L3402 (K052378)** manufactured by **Besteam and Proasia, respectively.**

There are minor differences in performance specifications of the scooters, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **Besteam** believes that the **LANDLEX P100X** scooter is substantially equivalent to legally marketed devices currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 14 2006

Mr. Jack Chen
Besteam Technology Inc.
No.16-1, Ziqiang 1st Rd.,
Zhongli City,
Taoyuan Hsien, Taiwan, 32063

Re: K060042
Trade/Device Name: LANDLEX P100X
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: January 03, 2006
Received: January 06, 2006

Dear Mr. Chen:

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,

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

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **LANDLEX P100X**

Indications for Use:

The **LANDLEX P100X** scooter is motor driven, indoor and outdoor transportation vehicles with the intended use to provide mobility to disabled or elderly persons limited to a seated position.

Prescription Use _____ Over-The-Counter Use __X__

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

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

510(k) Number K060042

(Posted November 13, 2003)