K991835

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DEC 20 1999

510(k) Summary
for
Hang Ups InvertAlign

Submitter: Roger C. Teeter
Hang Ups Div. of STL International, Inc.
10004 – 162nd St. Ct. E
Puyallup, WA 98375
Phone: (253) 840-5252
Fax: (253) 840-5757

Contact: Same as above.

Date prepared: December 17, 1999

Name of device: Hang Ups InvertAlign

Common or Usual Name: Rotation-Powered Gravity-Assisted Traction Table, Inversion Table

Classification Name: Equipment, Traction, Powered

Predicate Devices:

F5000-Series	510(k) Exempt	HST
InverChair	K821002	ITH
Vax-D	K951622	ITH
ATT-300	K944699	ITH
Midland Vari-trac II	K862746	ITH

Device Description:

The InvertAlign is a non-invasive traction device that utilizes gravity to apply traction. The user straddles the main shaft of the InvertAlign and while resting his seat on the base of the table frame, the user places each foot on the foot platform. The user's ankles slide between the foam padded ankle clamps. In the InvertAlign's full upright position, the user will be reclined in the supine position at approximately 10 degrees off vertical. By pulling the locking pin and locking the clamps securely to the ankles, the user or supervisor is able to manually adjust the foam clamps to form a secure but comfortable fit. The user or supervisor may then use the tilt control button to increase / decrease the angle of inversion. The InvertAlign can be stopped at any angle and is able to tilt beyond ninety degrees from horizontal to allow the user to hang and move freely at full inversion.

Intended Use:

The InvertAlign is a non-invasive traction device that utilizes gravity to apply traction. The traction force is a result of the natural force of gravity, and is affected only by the user's

(510(k) Summary, cont.)

body weight and angle of inversion. The InvertAlign is indicated to increase intervertebral dimensions, to decrease pressure on the intervertebral discs, to stretch and relax muscles, and to temporarily relieve back pain associated with the listed conditions. Explanations for these claims are found in Appendix C.

Technological Characteristics:

The InvertAlign is a gravity-assisted traction device. The traction force applied to the body is a measure of the user's weight and angle of inversion. The InvertAlign itself does not apply a mechanical force to the body. The device to which the InvertAlign is most similar is the F5000III Inversion Table. Essentially, the only difference between these two devices is that the InvertAlign is operated by a motor. The InvertAlign tilts with the help of motorized controls, whereas the F5000III uses the body's arm movements to control the angle of inversion. With the motor, this upgraded inversion table no longer requires the users to adjust the table to individual height settings, reducing the possibility of user error.

Another device to which the InvertAlign is very similar is the InverChair. The main difference between these two devices is the body position in which the device places the user. The InverChair is a motorized device which inverts the patient in a 90/90 position (seated). The InvertAlign inverts the user in a standing, supine position. By allowing for a full-body inversion experience, the InvertAlign gives the body a chance to stretch and perform body-enhancing exercises.

The other three devices to which the InvertAlign is compared, the Vax-D, ATT-300, and Midland Vari-trac II, physically apply a traction force to the body. This is the vital difference between these devices and the InvertAlign—the InvertAlign allows for a *natural* form of traction, whereas the Vax-D, ATT-300, and Midland Vari-trac II make use of a mechanically applied form of traction. The InvertAlign is a safer alternative form of traction because it relies on gravity and the user's body weight to apply the traction force. The InvertAlign is easy to use and does not require the help of a medical supervisor to operate. The InvertAlign may be returned upright at any time and requires only one user-sensitive adjustment—the foot clamps must be fitted to the users' ankles.

Summary of Safety and Effectiveness:

Inversion has been used since the age of Hypocrites and has been widely accepted as a natural form of traction in the United States since the 1960's. The fundamental purpose of the Hang Ups InvertAlign is to permit the application of inversion traction to the ankles, knees, hips and spine (all weight-bearing joints). The important attributes contributing to the safety and effectiveness of the device include the easy-to-use controls which require only one user-specific adjustment (i.e.: adjustable ankle clamps), the moderate, controlled rate of inversion and ascension, and the use of gravity to apply a *natural* and non-invasive traction force to weight-bearing joints. The emergency ascension crank may be used in the event of a power outage to return the user to an upright position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2000

Mr. Roger C. Teeter
STL International, Inc.
10004 - 162nd Street, Ct. E.
Puyallup, Washington 98375

Re: K991835
Trade Name: Hang Ups InvertAlign
Regulatory Class: II
Product Code: ITH
Dated: December 17, 2000
Received: December 17, 2000

Dear Mr. Teeeter:

This letter corrects our substantially equivalent letter of December 20, 1999, which incorrectly identified your device as a prescription use device on the indications for use enclosure.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

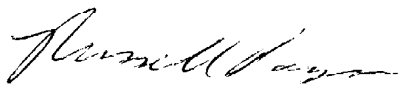
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K991835

Device Name: InvertAlign

Indication for Use:

Hang Ups InvertAlign is intended to be used for inversion, a method of gravity-assisted traction that utilizes the user's own body weight. Inversion is indicated to: increase intervertebral dimentions, decrease pressure on the intervetebral discs, stretch and relax muscles, and temporarily relieve back pain associated with the listed conditions.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)

Ronald Sager
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K991835

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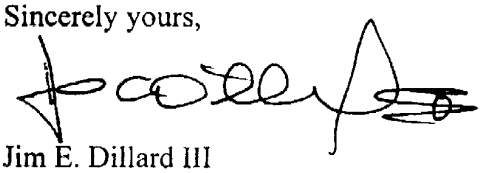

Jim E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure