NOV - 2 2000

K002390

Health Care Specialty

510(k) SUMMARY

LSI INTERNATIONAL, INC.

July 31, 2000

Submitter Information:

LSI International, Inc.
8849 Bond
Overland Park, KS 66214

Submitter's Name:	James C. Lane
Phone:	913/894-4493

Device Names:

Proprietary Name:	Quantum Intersegmental Roller Traction Table
Common Name:	Intersegmental Roller Traction Table
Classification Name:	Multi-functional Physical Therapy Table

Predicate Device Equivalence:

Substantial equivalence is claimed to the Quest Intersegmental Roller Traction Table, cleared for commercial distribution per K993461.

Indications: The Quantum Intersegmental Roller Traction Table is designed to release muscle tension and deliver a soothing massage.

Description: The Quantum Intersegmental Roller Traction Table features three six inch wide, six inch diameter rollers which rotate in a clockwise or counter-clockwise direction while tracking up and down the back. The roller height can be adjusted to place varying degrees of pressure on the muscles of the back while the patient is lying in the supine position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. James Lane
CEO
LSI International, Inc.
8849 Bond
Overland Park, Kansas 66214

Re: K002390
Trade Name: Quantum Intersegmental Roller Traction Table
Regulatory Class: Class II
Product Code: JFB
Dated: October 10, 2000
Received: October 11, 2000

Dear Mr. Lane:

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 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 (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,

for 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

510(k) Number (if known) K002390

Device Name: Quantum Intersegmental Roller Traction Table

Indications for Use:

The Quantum Intersegmental Roller Traction Table uses a roller mechanism and electric motors coupled with vibration and optional heat to release muscle tension and deliver soothing massage by the movement of the roller carriage back and forth from the cervical area to the lumbar area of the patient.

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

Concurrence of CDRH, Office of Devi ce Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002390

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

Optional Format 1-2-96