JUN 24 1998

K981822

PROFESSIONAL DISTRIBUTION SYSTEMS, INC.

PDS Inc. is a wholly owned subsidiary of Cluster Technology, Corp., a public company, trading symbol CLTT.

SECTION VII

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

[As required by 21 CFR 807.92]

Name of Manufacturer:

Professional Distribution Systems, Inc.
1160 South Rogers Circle, Bldg. A
Boca Raton, FL 33487
Tel: (561) 988-1747 / Fax: (561) 988-0967

Contact Person:

David Williams, President & CEO
Professional Distribution Systems, Inc.
Tel: (561) 988-1747 / Fax (561) 988-9067

Date of Summary Preparation:

May 21, 1998

Device Description:

Device Proprietary Name:	DRS System
Common Name:	Traction Equipment
Classification Name:	Power Traction Equipment
Class and Reference	Class II (21 CFR Section 890.5900)
Product Code:	89ITH
Panel Code:	87ORS

Predicate Devices:

K844385 Tru-Trac 401 Traction – Henley International
K951622 VAX-D® Therapeutic Table – Vat-Tech, Inc.

Device Description:

The DRS System™ is designed to apply distraction forces to a patient's lumbar spine.

The key elements are as follows:

1. The bed is a stand on/stand off tilt type bed that allows the fully clothed patient to step onto a footrest while it is in near vertical position. The bed and patient can then

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be slowly lowered to the horizontal treatment position using a remote controller hand held by the practitioner.

2. Once in the horizontal position the bed can be raised or lowered to the practitioner's preferred treatment height via the same hand held remote controller.
3. The bed is split into two cushions, each slideable in the horizontal plane only on low friction runners and each being able to be locked independently.
4. Distraction tensions are applied to the patient via a pelvic harness while the upper body of the patient is anchored to the locked upper (cephalic) cushion via a chest harness and adjustable underarm supports. The lower cushion, which is unlocked and on which the patient's lower trunk is rested, is able to slide easily thus reducing almost completely any frictional movement between patient and bed cushion when distraction tensions are applied, this concentrates virtually all the forces to the affected part of the lumbar spine.
5. The distraction unit (Vertrac) is mounted to a vertical movable platform incorporated into a support tower (Omni Tower) at the foot end of the bed. This enables the distraction tensions to be applied at differing angles to the patient (between 0 and 30 degrees).
6. The "Vertrac" unit is programmed and controlled from a control panel fitted into the "Omni Tower" to give static or intermittent distraction.
7. The minimum and maximum distraction settings are 0-200 lbs..
8. Treatment parameters i.e. tensions and time are continuously monitored and shown by LCD readout at the time of treatment set up and during treatment.
9. At the conclusion of treatment time, tension always returns to zero.
10. A cassette player, which is incorporated in a separate section of the control panel, and wireless headphones together with an overhead fluorescent "black light" provide comfort and relaxation to the patient.
11. There is instantaneous release of all tensions if the patient pushes the button on the hand held Patient Safety Switch, or the Stop Button on the control panel has been pushed by the practitioner.
12. The DRS System™ will not operate if the Patient Safety Switch is not working properly or has not been tested prior to each treatment.
13. The treatment cannot be restarted when a patient activates the Patient Safety Switch or the Stop Button has been pushed during treatment unless all treatment parameters are manually re-entered into the controller.

Intended Use

The DRS System™ provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the DRS System and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through

SUMMARY OF SAFETY AND EFFECTIVENESS

decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Technological Characteristics

The DRS System™ incorporates various principles and working characteristics of the predicate devices, Tru-Trac 401 Traction Device (K844385) and the VAX-D Therapeutic Table (K951622). The incorporating of the traction device and a flat surface type powered bed, whilst giving a new overall appearance to the apparatus, has not impacted on or changed the safety of effectiveness of the devices.

Clinical trials carried out by VAX-D endorse the principle of decompression; however, enclosed are extracts from study papers carried out using The DRS System™ , which further confirms same. (See Bibliography on Page 5 of this Section.)

We will further confirm that this summary contains only information that is within the main body of the 510(k), and no unsubstantiated labeling, claims, raw data, trade secrets, or patient identification information.

Summary of Safety and Effectiveness

The principles of operation the DRS System™ are such that it permits the usefulness of effective distraction tensions to the lumbar spine. The more important safety features include:

1. The activation of pillars and actuators for the bed are via a 24-volt electrical circuit.
2. The control circuitry for the distraction unit including the power supply to the Patient Safety Switch is a maximum 24 volts.
3. The patient is automatically reclined to the treatment position rather than climbing onto the treatment bed.
4. Adjustable handgrips are fitted for the patient to hold while the bed is being slowly reclined.
5. There is instantaneous release of all tensions when the button on the hand held Patient Safety Switch is depressed, the Stop Button is pressed on the control panel, or when electrical current is interrupted. The treatment program cannot be automatically restarted when any of those items in no. "5" have occurred without the full treatment parameters being manually re-entered into the control panel.
6. All treatment parameters must be manually entered each time a treatment occurs.
7. There is a limited vertical movement of the traction box.
8. There is a permanent, visible means of indication of the angle of distraction pull.
9. There is an audible warning signal when the unit is first turned on, when the treatment is completed, when the Patient Safety Switch is tested, when the Patient Safety Switch is activated during treatment, and when the entered treatment distraction parameter exceeds 39 lbs. force of tension.

Professional Distribution Systems, Inc. June 17, 1998
DRS System™ - 510(k) Notification

SUMMARY OF SAFETY AND EFFECTIVENESS

The Tru-Trac 401 has been in use in this country for more than ten years and we have no evidence of a MDR report being filed by the manufacturer nor have we been made aware of any events or conditions effecting the operation of this equipment during all trials carried out by PDS.

SUMMARY OF SAFETY AND EFFECTIVENESS

Bibliography of Extracts from Study Papers Carried Out Using the DRS SYSTEM.

1. Shealy, C. Norman, and Borgmeyer, Vera (1997)
Decompression, Reduction, and Stabilization of the Lumbar Spine: A Cost Effective Treatment for Lumbosacral Pain.
American Journal of Pain Management, Vol. 7, p. 63-65.

2. Shealy, C. Norman, and LeRoy, Pierre L. (1998)
New Concepts in Back Pain Management: Decompression, Reduction, and Stabilization.
St. Lucie Press, Boca Raton, FL. Chapter 20, p. 239-257.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 1998

Mr. David Williams
President & CEO
Professional Distribution Systems, Inc.
1160 South Rogers Circle, Building A
Boca Raton, Florida 33487

Re: K981822
Trade Name: DRS System
Regulatory Class: II
Product Code: ITH
Dated: May 21, 1998
Received: May 22, 1998

Dear Mr. Williams:

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 (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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Professional Distribution Systems, Inc.
DRS System™ - 510(k) Notification

June 17, 1998

510(k) Number (if known): K981822

Device Name: DRS System

Indications For Use:

Intended Use

The DRS System provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment consists of a physician prescribed treatment period on the DRS System and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain. It relieves pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981822

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