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Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-98-23

January 23, 1998

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

Dear Mr. Williams:

We are writing to you because on August 18 through 28, 1997, Investigator Michelle S. Dunaway from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the product known as the "DRS System". This product is manufactured, distributed, and promoted by your firm, Professional Distribution Systems, Inc. (hereafter PDS), which is a subsidiary of Cluster Technology Corporation. The "DRS System" consists of the following components: (1) A TruTrac 401 Traction Unit, manufactured by Henley Healthcare, Sugar Land, Texas, which PDS calls the Vertrac Unit; (2) the Omni Tower, manufactured by PDS, which is a vertical column that houses and controls the traction unit (via the Main Control Panel), and to which is attached a Patient Light Bar; and (3) a Powered (patient) Table manufactured by PDS. The PDS Powered Table is integrated to the Omni Tower via a laser light attached to the table which illuminates a reference point on the Omni Tower, which in turn identifies the angle of pull of the Vertrac Unit. The table is also integrated to the Omni Tower/Vertrac Unit via the patient, who is pulled by the Vertrac Unit while being secured to the table.

We understand that the "DRS System" could also include the optional "Microlight 830 Cold Laser", also manufactured by Henley Healthcare (previously Lasermedics, Inc.), which is an Investigational Device being offered "on a limited basis under an approved IRB protocol headed by C. Norman Shealy, M.D.". However, we understand that the Microlight 830 is not routinely sold with the DRS System; therefore, for the purposes of this discussion, we will consider the Microlight 830 separately, and our reference to the "DRS System" hereafter in this letter excludes the Microlight 830 Cold Laser.

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Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (Act), the DRS System and the Microlight 830 Cold Laser are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance by way of a Premarket Notification Submission [510(k)] for their products from FDA before they may offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records do not show that PDS obtained marketing clearance before it began offering the DRS System for sale. The kind of information PDS needs to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether this product may be legally marketed. Specifically, the FDA believes that the DRS System is a **new** device requiring a 510(k) under Title 21, Code of Federal Regulations (CFR), Part 807.81(a)(1) or (2). See page I-1 of the enclosed materials.

Because PDS does not have marketing clearance from FDA, marketing the DRS System is a violation of the law. In legal terms, the product is adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. The product is adulterated under the Act because PDS did not obtain premarket approval based on information developed by the firm that shows the device is safe and effective. The product is misbranded under the Act because PDS did not submit information that shows its device is substantially equivalent to other devices that are legally marketed.

The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Devices regulation was superseded on June 1, 1997, by the Quality Systems regulation, which incorporates the device GMP.

The inspection revealed that the DRS System is adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Current Good Manufacturing Practice (GMP) requirements of the Quality System (QS) regulation. These violations include, but are not limited to the following:

- Failure to document in the Device History Record (DHR) the results of the installation and inspection tests, e.g., reportedly this testing was documented by the technician's signature on the packing list, which also reportedly is maintained at Cluster Technology Corporate office. During the inspection on a later date, the investigator discovered a record entitled, "Installation Test Procedure", however, no one at the facility could explain where it came from or its use; DHR's also were found to contain discrepancies that show assembly of the same device on different dates and a lack of documentation of corrective actions taken during the installation or repair of different devices.
- Failure to document when a complaint requires further investigation and/or is reportable as a complaint or under the Medical Device Reporting (MDR) system, to document corrective actions taken, and to document replies to complainants in the record of the investigation, e.g., notes documenting contacts concerning error messages received from users that their devices failed after installation (serial nos. 10506-LBM-L1-6 and 10509-LBM-L1-3), a report of a blown fuse for DRS unit serial no. 10506-LBM-L1-6, and lack of documentation that these events were adequately evaluated as complaints.
- Failure to establish and document adequate procedures, and conduct planned and periodic quality audits of the quality assurance system.
- Failure to establish and implement written procedures for Medical Device Reporting requirements pursuant to 21 CFR Part 804, for control, evaluation, and investigations of nonconforming product, for the responsibility to evaluate and dispose of nonconforming product, for the rework and servicing of devices, and for the change implemented to effect corrective or preventive actions.

During the referenced inspection, PDS representatives informed Investigator Dunaway that:

- A. The Henley TruTrac 401 Traction Unit and the PDS Powered Table are considered to be stand alone devices because they are not electrically connected;
- B. A 510(k) is not needed because:

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1. The traction unit has a 510(k), K844385, and
 2. The Powered Table is exempt from submitting a 510(k) (under 21 CFR 890.3760);
- C. If a 510(k) is required, the 510(k) for the traction device component should cover the DRS System traction equipment.

The above PDS positions are incorrect as follows:

As stated above, the Henley TruTrac 401 Traction Unit and the PDS Powered Table are integrated. Both work together to achieve the intended uses of the DRS System, which uses cannot be accomplished by either alone. So while the Henley TruTrac 401 and the PDS Powered Table could be stand alone devices, they are not used so in this instance, i.e., they are used together as a "system". In addition, there is the Omni Tower, which is also a part of the "system", which PDS does not speak to.

K844385 covers the Escotek EST Trac Model 401 traction unit manufactured and distributed by Nor-Am Patient Care Products, Ontario, Canada, for the following intended uses:

- A. Simple static traction; and,
- B. Intermittent traction in progressive or regressive modes, with or without cycling.

The labeling, including promotional material, for the "DRS System" includes the following additional intended uses:

1. Low back pain relief;
2. Degenerated disc;
3. Facet disease;
4. Herniated disc;
5. Sciatica;
6. Joint mobilization;
7. Myofascial release and ligamentous stretch;
8. Offering pain relief to a host of patients ... whom you couldn't help before;

9. Achieving the delicate balances never possible before in therapies addressing the lowering of intradiscal pressure of the lumbar spine;
10. Successful delivery of treatments indicated for "most" conditions associated with lower back pain;
11. Reduction of painful herniation and other disc related degenerative conditions;
12. Diffusion of nutrients into the disc space is enhanced;
13. After 3 weeks of treatment, clinical studies have shown outstanding results in relieving the debilitating pain caused from ... many failed back surgery cases;
14. Patients with diagnosis consistent with ... spinal stenosis are candidates for treatment;
15. Post-surgical patients who do not have significant compromise or spinal stability are candidates;
16. "Significantly" distracting the lumbar spinal segments and producing negative intradiscal pressure, which could then theoretically pull the herniated segment back, thus relieving neurocompression;
17. Intervertebral spaces open during the procedure to reduce displacement of the protruding disc;
18. The changes in pressure surrounding the lumbar disc through the cycling action of the machine facilitates blood flow through the disc. Fresh blood, oxygen, and nutrients flow in while cations, acids, and the breakdown products of metabolism are removed. Thus natural healing and repair can proceed in tissues that previously were encumbered with high diffusion pressure, edematous tissues, and chronic irritation;
19. Helped chronic degenerated disc patients return to an active, pain-free lifestyle;
20. "Most" patients having lower back pain can be treated;
21. Patients with multiple herniations respond well;
22. Herniations respond most favorably when MRI shows lateral herniation with impingement. Mild central bulging takes a much longer treatment time;

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23. Sciatica usually resolves in the first week;
24. Early facet arthropathy may quickly resolve with a "pop" sensation;
25. Spinal stenosis - if caused by herniation, degeneration, of facet arthropathy can be treated;
26. DRS increases axonal nutrient flow through the spinal nerve, allowing for increased flow, which decreases nerve diameter through the narrow canal;
27. Post surgical pain;
28. Simple laminectomies can be treated after 6 months; and,
29. The Vertrac is set at 10 degrees elevation for L5, 20 for L4 and 30 for L3, and if the patient had previous surgery or long standing diseases, they usually benefit from starting between 20 - 30 degrees for all levels.

Regardless of the merits of your claim that Henley Healthcare acquired the rights to 510(k) K844385, the above 29 additional intended uses that the "DRS System" is labeled for are not covered by this 510(k). These 29 uses represent "a major change or modification in the intended use of the device", which would require a new 510(k) by the manufacturer (Henley) under 21 CFR 807.81(a)(3)(ii). See page I-1 of the enclosure. The only way PDS could be exempt from submitting a 510(k) for the Henley device would be if, after putting its own name on the device, PDS did "...not change any other labeling or otherwise affect the device...", and if the device did not otherwise require a 510(k). See 21 CFR 807.85(b) on page I-2 of the enclosure. Clearly, PDS has changed the labeling. And, considering that PDS has moved the controls for the Henley device proper to the "Major Control Panel" on the Omni Tower, PDS affected the traction unit itself.

For your information, while a "Powered Table" is exempt from 510(k) submission under 21 CFR 890.3760, the regulation states a Powered Table "is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position." The above referenced intended uses for the "DRS System" (1-29) fall outside this exemption. Therefore, when used for these purposes, the PDS Powered Table would require a 510(k). See enclosed copy of 21 CFR 890.9 for the limitations on exemptions from Section 510(k).

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You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties (see below). Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

With respect to civil money penalties, the FDA may assess these against you individually and PDS, for violations of Section 301(a) of the Act, i.e., the introduction or delivery for introduction into interstate commerce of any ... device ... that is adulterated or misbranded. Under Section 303(g)(1)(A) of the Act, FDA may impose civil penalties of up to \$15,000 on you as an individual, and a like amount on PDS, for each violation of a requirement of the Act relating to medical devices, up to a total of \$1,000,000 per respondent for all violations. In this case, a violation of referenced Section 301(a) occurs each and every time PDS ships a device.

With respect to the Microlight 830 Cold Laser, which you claim is an Investigational Device, PDS's promotion of this device and representations that it is safe and effective for Carpal Tunnel Syndrome and low back pain, in labeling for the DRS System, are violations of enclosed Sections 21 CFR 812.7(a) and (d), respectively, of the Investigational Device Exemption (IDE) Regulation. You must comply with all of the requirements of enclosed 21 CFR 812.2(b)(1)(vii), including the requirement to comply with the prohibitions in 21 CFR 812.7, to be considered to have an approved IDE application. Absent an approved IDE or Premarket Approval Application (PMA), or a 510(k) determination of substantial equivalence, the Microlight 830 Cold Laser is in violation of Sections 501(f)(1)(B) and 502(o) of the Act.

It is necessary for you to take action on these matters now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need additional time, let us know why and when you expect to complete your correction. Please direct your response to Mr. Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains to the issue of premarket clearance for your

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device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Tim Couzins at (407) 648-6823, ext. 264.

Sincerely,



Douglas D. Tolen
District Director
Florida District

Enclosures

cc: Mr. Michael M. Barbour
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