K951622

JUL – 2 1996

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **SPONSOR IDENTIFICATION**

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2. **SPONSOR ESTABLISHMENT REGISTRATION NUMBER:** 8022271

3. **OFFICIAL CONTACT PERSON**

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4. **DATE OF PREPARATION OF SUMMARY:** June 11, 1996

5. **DEVICE INFORMATION**

A.	**DEVICE PROPRIETARY NAME:**	VAX-D® Therapeutic Table
B.	**COMMON NAME:**	Traction Equipment, Powered
C.	**CLASSIFICATION NAME:**	Equipment, Traction, Powered
D.	**CLASS AND REFERENCE:**	Class II (21 CFR Section 890.5900)
E.	**PRODUCT CODE:**	89ITH
F.	**PANEL CODE:**	87OR

6. **PREDICATE DEVICE:** VAX-D® (or "VAX-T® ") Therapeutic Table (K894435)

7. **DEVICE DESCRIPTION**

The VAX-D® Therapeutic Table is designed to apply distraction tensions to the patient's lumbar spine. The patient lies on the table in a prone position; the upper body is on the stationary portion of the table and is restrained by the patient holding on to adjustable hand grips. The table is a split-table design, whereby distraction tensions are applied to the patient through a pelvic harness attached to a tensionometer and by the separation of the movable part of the table. The VAX-D® Therapeutic Table provides automated or varied timed distraction-relaxation cycles. For safety, the patient holds on to the handgrip which can be released at any time to end the session and restore full relaxation. Distraction tensions and rates are continuously monitored and measured by the tensionometer attached to the pelvic belt, and the output is shown on a digital gauge and captured on a pen-writer printout, or optionally through direct connection to a computer terminal. The chart recording forms a permanent record of the treatment parameters, which becomes part of the patient's chart.

8. **INTENDED USE**

The VAX-D® Therapeutic Table is designed to relieve pressure on structures that may be causing low back pain. It relieves the pain associated with herniated discs, degenerative disc disease, posterior facet syndrome and radicular pain. It achieves these effects through decompression of intervertebral discs, that is, unloading, due to distraction and positioning.

9. **INDICATIONS FOR USE**

This therapy provides a primary treatment modality for the management of pain and disability for patients presenting with incapacitating low back pain. It has been found to provide relief in a variety of conditions involving anatomical dysfunctions of the lumbar spine that generate localized low back pain as well as peripheral radiation, including patients with protruding or herniated intervertebral discs, degenerative discs as well as those with acute facet problems.

10. **TECHNOLOGICAL CHARACTERISTICS**

The VAX-D® Therapeutic Table is essentially the same product as the predicate device, VAX-T® Therapeutic Table (K894435). VAT-TECH, INC. has made some minor modifications in the appearance and components used in The VAX-D® Therapeutic Table since its introduction in 1989. Each of these changes was evaluated by VAT-TECH and found not to impact the safety or effectiveness of this device. The changes include changes in appearance, replacement of timers and replacement of cycle counters.

11. SUMMARY OF SAFETY AND EFFECTIVENESS

The operating principles of the VAX-D® Therapeutic Table permit application of effective distraction tensions to the lumbar spine. The important basic parameters contributing to the safety and effectiveness of the device include the use of air pressure as the energy source, the ramp characteristics employed in applying distraction tensions, the release rate of tensions and relaxation cycles, the cyclic periodicity, the upper limits on distraction tensions and, in addition, the positioning of the patient and the means of fixing the upper body. The fact that the patient can, at will, release all tensions completely and immediately through releasing the hand grips, is an important safety factor. The VAX-D® Therapeutic Table has been in clinical use since 1989. VAT-TECH maintains contact with the clinics administering the therapy, and our professional staff provides ongoing advisory services to these clinics. We would, therefore, be aware of events and conditions affecting the operation of this equipment and, in the past seven years, have not filed a single MDR report, which reflects on the inherent safety of the device.