DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 13, 2015

Hollywog, LLC
Michael Treas
Chief Compliance Officer
2830 Ammicola Highway
Chattanooga, Tennessee 37377

Re: K150695
Trade/Device Name: Modpod
Regulation Number: 21 CFR 890.5900
Regulation Name: Power Traction Equipment
Regulatory Class: Class II
Product Code: ITH
Dated: July 9, 2015
Received: July 10, 2015

Dear Mr. Treas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150695

Device Name
Modpod

Indications for Use *(Describe)*
Modpod cervical traction provides mobilization of skeletal structures and muscles in static, intermittent, progressive, and regressive distraction forces to relieve pressures that may be causing pain of skeletal or muscular origin. These effects are achieved through decompression of intervertebral discs, that is, unloading due to distraction and positioning, and may be used to relieve peripheral radiation/sciatica and pain associated with:

•Protruding discs
•Bulging discs
•Herniated discs
•Degenerative disc disease
•Posterior facet syndrome
•Acute facet problems
•Radicular pain
•Prolapsed discs
•Spinal root impingement
•Hypomobility
•Degenerative joint disease
•Facet syndrome
•Compressions fracture
•Joint pain
• Discogenic pain

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary per 21 CFR; 807.92
510(k) K150695

510(k) SUBMITTER:	Hollywog, LLC
ESTABLISHMENT REGISTRATION:	3008585473
CONTACT:	Michael W. Treas Chief Compliance Officer Telephone (423) 305-7778 Fax (423) 305-7867
DATE PREPARED:	July 9, 2015
PROPRIETARY NAME:	Modpod™
PANEL:	Physical Medicine
REGULATION NUMBER:	CFR Title 21, 890.5900
CLASSIFICATION:	Class II
PRODUCT CODE:	ITH
REGULATION DESCRIPTION:	Power traction equipment
COMMON NAME:	Cervical traction

The Modpod™ Cervical Traction Device provides static and intermittent distraction forces to the cervical spine to relieve pressures on structures that may be causing pain of skeletal or muscular origin. Therapeutic distraction can be applied in a variety of programmable patterns and functions.

The device design allows a clinician access to a patients head and neck when hands-on interaction and positioning is needed. Use of the device reduces the level of exertion experienced by the clinician when compared to manual traction therapy techniques. Additionally, hands-on interaction and positioning by the clinician may occur before or after treatment.

Legally marketed devices to which substantial equivalence is claimed:

510(k) #	*Predicate Proprietary Trade Name*	*Predicate Regulation*
K051938	Triton®/Tru-Trac®/TX™ Traction	CFR Title 21, Sec. 890.5900, Class II, ITH
K053223	Triton®/Tru-Trac®/TX™ Traction	CFR Title 21, Sec. 890.5900, Class II, ITH

The indications for use are substantially equivalent to the claimed predicate devices. Differences between indications for use do not affect safety or effectiveness when used as labeled and as intended. The intended patient population is adults of all ages.

The power supply is an off-the-shelf wall plug type that complies with the IEC 60601-1:2005 Ed.3 standard. The power supply steps down mains voltage to 12VDC and solely serves to charge the lithium ion batteries. The device operates exclusively from the batteries whether the power supply/battery charger is used or not used. The power supply/battery charger automatically switches 100-240VAC +/- 10%; 47-63Hz; 1 Phase; Current 0.9A @ 100VAC to accommodate most electric power service systems worldwide.

If the device is plugged into mains power and not in use the battery is constantly trickle charged. If the device is being used while plugged into mains power the electronic design allows any unused energy from mains power to charge the batteries. The device uses a charging IC to control and regulate charging of the batteries to ensure the batteries do not overcharge. If the device is operating solely on battery power (not plugged into mains power) no charging occurs. The battery voltage is monitored and the battery life status is displayed on the screen. Once the voltage is discharged to near the minimum voltage needed to run the charging IC; the device display screen shows an error and uses an audible tone to alert the clinician the battery needs to be plugged into mains power for charging.

A clinician interfaces with the device through a touch display screen. The electronics and software control the actuator. The device includes an electronic load cell calibrated during the manufacturing process. Subsequent calibration is not be required because the electronics tare/set the load cell to zero each time the device is turned on. Traction forces are administered by an electromechanical linear actuator with a brush-type DC motor. The device is intended for therapeutic care on an outpatient basis. Monitoring technology maintains the set traction force if a patient were to shift or move during a treatment. The actuator has the capability to operate at 12 Volts; the design requires only 4 volts to achieve the desired speed and to lessen the operating noise level. The design uses plastic gears in the actuator to reduce noise. There is no additional voltage generated above that of the batteries, and no components are operated outside their specified ratings. Additionally, the actuator has an internal encasement plus the device encases the actuator. Therefore, the plastic actuator gears are double encased for a high degree of noise reduction. Sound measured during operation of the device measured in the proximity of a patient's ear ranged from 26db to 56db when the actuator is in operation; to virtually no observable sound when the actuator reaches the treatment set point.

The treatment should only be administered under the presence of a doctor or therapist. The doctor or therapist should be present at all times and supervise the treatment carefully. Never leave the patient alone during the treatment. Use care on patients who do not tolerate supine positions, as they may not be good candidates for traction therapy. There are two types of head harnesses. One head harness has a chin strap; the other does not have a chin strap. The head harness without a chin strap may be chosen by a clinician for their patients who experience discomfort related to pressure sensitivity related to Temporomandibular joint dysfunction (TMJ).

The head halter comes in Cotton Duct Fabric and PVC Coated Polyester Fabric both with Velcro® adjustment for ease of patient setup in the device. The device cushions are made of I-Skin Polyurethane. The cushion set consists of a Shoulder Support Cushion and Head Support Cushions in 10°, 15° and 20°.

Conclusion:
The Modpod cervical traction device is as safe and effective, and performs as well or better than the claimed predicate devices.

Technical Comparison Attached -

510(k)	K150695	K051938	K053223
Regulation Number	890.5900	890.5900	890.5900
Product Class	Class II	Class II	Class II
Product Code	ITH	ITH	ITH
Intended environment of use	Outpatient clinic	Outpatient clinic	Outpatient clinic
Indications for use	**Indications for use** Modpod cervical traction provides mobilization of skeletal structures and muscles in static, intermittent, progressive, and regressive distraction forces to relieve pressures that may be causing pain of skeletal or muscular origin. These effects are achieved through decompression of intervertebral discs, that is, unloading due to distraction and positioning, and may be used to relieve peripheral radiation/sciatica and pain associated with: • Protruding discs • Bulging discs • Herniated discs • Degenerative disc disease • Posterior facet syndrome • Acute facet problems • Radicular pain • Prolapsed discs • Spinal root impingement • Hypomobility • Degenerative joint disease • Facet syndrome • Compressions fracture • Joint pain • Discogenic pain	**Indications for use** The Triton/Tru-Trac/TX traction devices provide traction and mobilization of skeletal structures and skeletal muscles. The Triton/Tru-Trac/TX traction devices provide a treatment in static, intermittent, progressive, regressive and cycling distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder). Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions. The Triton/Tru-Trac/TX traction devices may be used to relieve peripheral radiation/sciatica and pain associated with: • Protruding discs • Bulging discs • Herniated discs • Degenerative disc disease • Posterior facet syndrome • Acute facet problems • Radicular pain • Prolapsed discs • Spinal root impingement • Hypomobility • Degenerative joint disease • Facet syndrome • Compressions fractures • Joint pain • Discogenic pain The Triton/Tru-Trac/TX traction devices achieve these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.	**Indications for use** The Triton/ Tru-Trac/TX/Triton DTS Traction devices provide traction and mobilization of skeletal structures and skeletal muscles. The Triton/ Tru-Trac/TX/Triton DTS Traction devices provide a treatment in static, intermittent, progressive, regressive and cycling distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder). Therapeutic distraction can be applied in a variety of programmable patterns., cycles and functions. The Triton/ Tru-Trac/ TX/ Triton DTS 'Traction devices with the optional EMG (a.k.a. sEMG) biofeedback feature may be used to relieve peripheral radiation/sciatica and pain associated with: • Protruding discs • Bulging discs • Herniated discs • Degenerative disc disease • Posterior facet syndrome • Acute facet problems • Radicular pain • Prolapsed discs • Spinal root impingement • Hypomobility • Degenerative joint disease • Facet syndrome • Compressions fractures • Joint pain • Discogenic pain EMG (a.k.a. sEMG) Determination of the activation magnitude and timing of muscles for: a) retraining of muscle activation b)coordination of muscle activation - Determination of the force produced by muscle for control and maintenance of muscle contractions.

			- Relaxation muscle training. -Muscle re-education
Intended Use	Decompression of intervertebral discs of the cervical spine.	Decompression of intervertebral discs of the cervical spine. Alternative uses for decompression of intervertebral discs of the thoracic or lumbar.	Decompression of intervertebral discs of the cervical spine. Alternative uses for decompression of intervertebral discs of the thoracic or lumbar.
Target Population	The intended patient population is adults of all ages.	The intended patient population is adults of all ages.	The intended patient population is adults of all ages.
Anatomical Site	Cervical spine	Cervical spine. Alternative uses for other anatomical sites.	Cervical spine. Alternative uses for other anatomical sites.
Maximum cervical traction tension force i.e., energy delivered	40 pounds	40 pounds	40 pounds
Human Factors	Rotating display screen for clinician ease for viewing	Rotating display screen for clinician ease for viewing	Rotating display screen for clinician ease for viewing
Design	Painted sheet metal and ABS plastic encasement housing electronic circuitry; software and electronics engage a gear driven motor with load sensors; slide mechanism, and patient head harness to apply cervical traction.	ABS plastic encasement housing electronic circuitry; software and electronics engage a gear driven motor with load sensors; rope mechanism, and patient head mechanism to apply cervical traction.	ABS plastic encasement housing electronic circuitry; software and electronics engage a gear driven motor with load sensors; rope mechanism, and patient head mechanism to apply cervical traction.
Electrical medical standards meet	AAMI/ANSI/ES 60601-1: 2005 Ed. 3/ IEC60601-1:2005 Ed.3 (FDA, Standard Recognition #19-5)	IEC60601-1:1988 Ed. 2 (FDA, Standard Recognition #5-4)	IEC60601-1:1988 Ed. 2 (FDA, Standard Recognition #5-4)
Electromagnetic compatibility i.e., compatibility with the environment and other devices	AAMI/ANSI/IEC 60601-1-2 :2007 Ed. 3 (FDA, Standard Recognition #19-2)	IEC 60601-1-2:2001 Ed.2 (FDA Standard Recognition #5-28)	IEC 60601-1-2:2001 Ed.2 (FDA Standard Recognition #5-28)
Preset protocols -	Yes	Yes	Yes
Protocol name:	Cervical TX	Disc Involvement with muscle guarding	Disc Involvement with muscle guarding
Protocol Speed (%):	30	30	30
Protocol total time (Min):	17	17	17
Progressive Stage - Traction type:	Static	Static	Static
Steps:	6	6	6
Hold (Sec):	10	10	10
Rest (Sec):	0	0	0
Traction Stage - Traction type:	Intermittent	Intermittent	Intermittent
Steps:	0	0	0
Hold (Sec):	60	60	60
Rest (Sec):	20	20	20
Time (Min):	15	15	15
Regressive Stage - Traction type:	Static	Static	Static
Steps:	6	6	6
Hold (Sec):	10	10	10
Rest (Sec):	0	0	0
Power source	Automatic switchable power supply 100-240VAC, 50/60Hz +/- 10% tolerance – charging a Lithium Ion Battery, 3.2V-3200mAh	Automatic switchable power supply 100-240VAC, 50/60Hz +/- 10% tolerance	Automatic switchable power supply 100-240VAC, 50/60Hz +/- 10% tolerance
Mechanical Safety - Traction force can be halted and traction tension released by a patient	Yes	Yes	Yes

held stop switch if the patient feels discomfort during traction therapy			
Steps down mains power to operate internal electronics and components at low voltage	Yes	Yes	Yes
Operates from battery source	Yes	No	No
Battery type	Rechargeable lithium ion 3200mAh	N/A	N/A
Software	Yes	Yes	Yes
Accessories	Patient head halter without ridged	Patient head halter with ridged bolsters	Patient head halter with ridged bolsters
Weight (lbs., oz.)	23.8lbs (10.8kg)	30 lbs (14 kg)	30 lbs (14 kg)
Dimensions (in.) [W x H x D]	15.5” (39.4cm)(W) x 11.0” (27.9cm)(H) x 30.3” (76.8cm)(D)	9.5 in (24 cm) (W) x 17.5 in (45 cm)(H) x 17.5 in (45 cm)(D)	9.5 in (24 cm) (W) x 17.5 in (45 cm)(H) x 17.5 in (45 cm)(D)
Enclosure Material and Construction	ABS plastic with screws	ABS plastic with screws	ABS plastic with screws
	Painted metal with screws	No exposed painted metal	No exposed painted metal
Actuation mechanism	The mechanism for actuation begins with a licensed clinician engaging the device electronic interface to activate the device software. The software and electronics engage a gear driven motor with load sensors; slide mechanism, and patient head harness to apply cervical traction. The load sensor detects the load cell voltage corresponding to the amount of traction force to a patient.	The mechanism for actuation begins with a licensed clinician engaging the device electronic interface to activate the device software. The software and electronics engage a gear driven motor with load sensors; rope mechanism, and patient head harness to apply cervical traction. The load sensor detects the load cell voltage corresponding to the amount of traction force to a patient.	The mechanism for actuation begins with a licensed clinician engaging the device electronic interface to activate the device software. The software and electronics engage a gear driven motor with load sensors; rope mechanism, and patient head harness to apply cervical traction. The load sensor detects the load cell voltage corresponding to the amount of traction force to a patient.
Thermal Safety	Double encased electronics and actuation mechanism	Double encased electronics and actuation mechanism	Double encased electronics and actuation mechanism
Noise	<60db maximum	<60db maximum	<60db maximum
DC motor parameters	Brush-type DC motor	Brush-type DC motor	Brush-type DC motor
	Variable speed by voltage	Variable speed by voltage	Variable speed by voltage
	Slower speed produces lower audible sound	Slower speed produces lower audible sound	Slower speed produces lower audible sound
Sterility	Intended use non-sterile	Intended use non-sterile	Intended use non-sterile
Chemical Safety	Intended use does not involve chemicals	Intended use does not involve chemicals	Intended use does not involve chemicals
Radiation Safety	Intended use in non-radiation environments	Intended use in non-radiation environments	Intended use in non-radiation environments
Biocompatibility	Modpod™ Cushion Set Polyurethane	Tru-Trac® Traction Bolster Set Polyurethane	Tru-Trac® Traction Bolster Set Polyurethane