

4/23/99

K981311

## 510(k) Summary

(21 CFR 807.92c.)

### APPLICANT

[As Required by 21 CFR 807.92 a(1)]

Applicant: KCI New Technologies, Inc.  
(NuTech)  
Establishment Registration No. 1648561

Address: 8023 Vantage Dr.  
San Antonio, TX 78230-4726

Telephone Number: 210-255-4468  
210-255-4450 fax

Company Contact: Judith Harbour  
Regulatory Affairs

Date: April 8, 1998

### DEVICE NAME

[As Required by 21 CFR 807.92 a (2)]

Proprietary Name: Cowboy XV  
(subject to change)

Common Name: Intermittent, External Pneumatic Compression  
Device

Classification Name: Compressible Limb Sleeve  
(per 21 CFR section 870.5800)

### CLASSIFICATION OF DEVICE

[As Required by 21 CFR 807.87(c)]

Review Panel: Cardiovascular

Classification: Class II

Product Code: 74JOW

### MANUFACTURING FACILITY

[As Required by 21 CFR 807.87(h)]

Kinetic Concepts, Inc.  
4958 Stout Dr.  
San Antonio, TX 78219

210-662-9191  
210-662-0215 fax

**IDENTIFICATION OF PREDICATE DEVICE**  
**[As Required by 21 CFR 807.92 a(3)]**

The predicate device to which substantial equivalence is being claimed is Cowboy X (a.k.a. **PlexiPulse® Acute Care Unit**), also manufactured for NuTech by KCI. The PlexiPulse® Acute Care Unit is the hospital version of Cowboy XV and has been in use at hospitals for approximately 6 years. The PlexiPulse® Acute Care Unit is a pneumatic compression device used for non-ambulatory, resting patients who require increased blood flow in the calf and foot.

The 510(k) number for Cowboy X is: K944567

**DEVICE DESCRIPTION**  
**[As Required by 21 CFR 807.92 a(4)]**

**General**

The Cowboy XV pump is connected through tubing to a foot wrap(s). When inflated, these wraps mimic the normal physiological actions of walking, thus helping to open up the circulation in the venules and arterioles in the lower extremities. For the patient, this improved blood flow means a greater chance of prolonging the time before or preventing the need for amputation as their wounds heal.

Cowboy XV functions as an **intermittent pneumatic compression device** that enhances lower extremity blood circulation. Cowboy XV is **not a life-supporting or life-sustaining device**. Cowboy XV is **not an implant** (short-term or long-term), **nor is it a sterile device**. Cowboy XV is an **electrically-operated** (designed to meet UL 1431), **software-driven, prescription device**, which is used in the **home environment**. Cowboy XV is comprised of two major components – the **reusable** pump unit and a **single-patient use** inflatable foot wrap. **Neither component contains a drug nor biological product as a subcomponent.**

Cowboy XV uses a 16 foot hospital grade power cord to supply a voltage of 115 volts AC at a frequency of 60 Hz with a maximum current consumption of 0.33 amperes and a maximum electrical leakage of less than 100 microamperes from its **power source**. An exterior shell made of **Prism CM-200 material**, measuring 12" long by 10 ¼ " wide by 7" deep, protects the subcomponents of Cowboy XV **11 pound** unit.

The compressor inflates one or more of the wraps in minimum intervals of 20 seconds at a maximum pressure of not more than 180 mmHg ( $\pm$  15 mmHg).

The unit **features** a microprocessor that controls the unit's operation. The frequency and intensity of the compressions, as well as the duration of the compression, are all preset values which are monitored and controlled by the microprocessor. The microprocessor also has **detection capabilities** to monitor the pressure in the wrap(s), adjusting the in and out flow of air on every cycle, to ensure that the target pressure is consistently maintained. If

for any reason the target pressure cannot be maintained, the microprocessor **alarm capabilities** will activate both visual and audio alarms. These **alarm capabilities** are built in to detect high pressure, low pressure, and/or unit malfunction situations, should they ever occur.

The **non-sterile** inflatable foot wraps are for **single-patient** use only. Each wrap is designed to fit around and compress the foot as well as the veins of the foot. Hook-and-loop fasteners are used to hold the foot wrap comfortably around the foot. The foot wrap is RF-welded to create an air chamber that can then be inflated by Cowboy XV. This air chamber is what actually applies pressure against the body.

### **STATEMENT OF INTENDED USE**

**[As Required by 21 CFR 807.92 a(5)]**

#### **Patient Population**

Cowboy XV is intended for patients with diabetic and arterial ulcers of the lower extremities.

#### **Indications**

Cowboy XV is designed to enhance blood circulation in the venules and arterioles in the lower extremities of patients with diabetic and/or arterial ulcers.

Cowboy XV is intended for patient's in the home who would benefit from increased blood flow to:

- treat and assist healing of cutaneous ulceration (wounds).
- reduce wound healing time.
- enhance arterial circulation (blood flow).
- prevent venous stasis (slowing of blood flow).
- reduce compartmental pressures.
- reduce edema (swelling).
- reduce post-operative pain and swelling.
- reduce the need for anticoagulant medications (medications that thin the blood).
- prevent Deep Venous Thrombosis (DVT) (blood clots in deep veins).

#### **Contraindications**

Patient conditions for which Cowboy XV is contraindicated include:

- presumptive evidence of congestive heart failure.
- suspected pre-existing Deep Vein Thrombosis (blood clots in deep veins).

#### **Differences in Indications**

The indications for Cowboy XV are the same as those for the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 4 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Judith A. Harboour  
Regulatory Assistant  
KCI New Technologies, Inc.  
8023 Vantage Drive  
San Antonio, TX 78230

Re: K981311  
Cowboy XV  
Regulatory Class: II (Two)  
Product Code: 74 JOW  
Dated: February 16, 1999  
Received: February 18, 1999

Dear Ms. Harbour:

This letter corrects our substantially equivalent letter of April 23, 1999, regarding the Cowboy XV compressible limb sleeve device. The indication for use form included in the original substantial equivalent letter has been revised to include the patient population for which the device was intended for.

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 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). 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 (Pre-market 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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS)

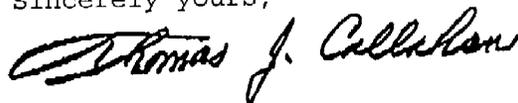
Page 2 - Ms. Judith A. Harboour

regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their 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,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known): K981311

Device Name: Cowboy XV

Indications for Use:

The Cowboy XV is designed to enhance blood circulation in the venules and arterioles in patients with diabetic ulcers of the lower extremities.

Cowboy XV is intended for patient's in the home who would benefit from increased blood flow to:

- treat and assist healing of cutaneous ulceration (wounds).
- reduce wound healing time.
- enhance arterial circulation (blood flow).
- prevent venous stasis (slowing of blood flow).
- reduce compartmental pressures.
- reduce edema (swelling).
- reduce post-operative pain and swelling.
- reduce the need for anticoagulant medications (medications that thin the blood).
- prevent Deep Venous Thrombosis (DVT) (blood clots in deep veins).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K981311

Prescription Use         
(Per 21 CFR 801.109)

OR

Over-The-Counter Use       

(Optional Format 1-2-96)