

K962239

Premarket Notification [510(k)] Summary

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Trade Name: Smart Adjuster
Common Name: Chiropractic Adjusting Unit
Classification name: Unclassified

Equivalent Device:

Force Recording and Adjusting System (FRAS). 510(k) Number K940085. Marketed by Sense Technology, Inc.

Description of the Device:

The Smart Adjuster is a device that is equivalent to the Force Recording and Analysis System (FRAS), 510(k) Number K940085. Below is a list of similarities and differences between the two devices. Both devices are designed to measure force rebound, display results and perform mechanical adjustments to the human spine. These types of adjustments are performed by chiropractors.

The Smart Adjuster consists of three distinct units. The first is a computer with software that controls the displays and settings of the hardware portion of the system. The hardware part of the system functions as a control unit for the hand held transducer unit. The transducer unit (head) is used by the doctor to sample the reaction of the spine and overlying tissue to the introduction of a measured percussive force. The reaction at the site of the percussion is recorded as a rebound force. That is, part of the percussive force is absorbed and dissipated by the patient's body and part of the force is rebounded to the point of entry back to the transducer. The difference is calculated and the rebound force is recorded and displayed as a single bar component of a histogram of several contract points over the patient's back coincident with the anatomical location of the vertebral segments. This allows the doctor to view a "map" of the dissipation and rebound of an application of a measured amount of force into the back of the patient.

The chiropractor, by virtue of education and training, can determine if and where an adjustive force should be applied to the patient in order to facilitate a "chiropractic adjustment" of the patient's spine. The force can be applied with the Smart Adjuster or by any other means normally available and used by chiropractors. When using the Smart Adjuster as an adjusting tool, the chiropractor may select a measured force, up to 35 pounds, and apply that force to a very specific location, determined by education and experience, on the patient. When the "adjustment phase" of the treatment is completed, the chiropractor precisely repeats the analysis phase. This device will again record and display the results and will then compare the results, as duplicate histograms, so the pre-adjustment and post-adjustment results may be observed.

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Intended Use of the Device:

This device will be used by chiropractors to as an additional analysis tool to help identify areas of fixation and/or subluxation of the human spine. Additionally, it will allow the doctors to perform mechanical adjustments to the human spine.

Comparison to Existing Device:

Please see ATTACHMENT B and TABLE B provided in the original submission and the amendments provided in this correspondence.