



HEALTH SENSE
INTERNATIONAL, INC.

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510(K) SUMMARY

IDENTIFICATION

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Date Summary Prepared

July 10, 1996

NAME OF DEVICE

Classification Name

Conditioned Response Enuresis Alarm

Common/Usual Name

Incontinence Alarm

Proprietary NameDryTime[®] for Bladder Control Silent**LEGALLY MARKETED DEVICE EQUIVALENT TO PROPOSED DEVICE**

DryTime[®] for Bladder Control Silent is substantially equivalent to the legally marketed predicate enuresis alarm, DryTime[®] for Potty Training (K955338), manufactured by Health Sense International, Inc., which is intended for daytime use by toddlers.

DESCRIPTION OF PROPOSED DEVICE

The proposed device, DryTime[®] for Bladder Control Silent, is a daytime enuresis alarm that may be used by an ambulatory adult to assist in controlling incontinence. It is designed and used in a manner consistent with the predicate device (*i.e.*, the emission of bodily fluids is detected when those fluids complete an electrical circuit in a sensor device and thereby set off an electronic alarm). DryTime[®] for Bladder Control Silent contains the identical components used in the Health Sense International predicate device, DryTime[®] for Potty Training, except that DryTime[®] for Bladder Control Silent uses a silent vibrator alarm in place of the audio buzzer alarm of DryTime[®] for Potty Training.

DryTime[®] for Bladder Control Silent is comprised of a disposable fluid sensor strip unit (Sense'R Strip[®]) attached to a silent vibrator alarm unit, which, in turn, clips via a soft vinyl strap to the front of the undergarment about two inches below the outside of the waistband (fabric is pinched to allow the jaws of clip to attach). The sensor strip unit is the identical Sense'R Strip[®] of the approved DryTime[®] for Potty Training predicate device, and includes two parallel vertical aluminized mylar sensor strips which are spaced a short distance apart from each other and which are electrically connected to the silent vibrator alarm unit. These aluminized mylar sensor strips are encased inside a disposable soft, absorbent paper sheath; the outer portion of the paper sheath is composed of apertured paper and the inner portion is made of a highly absorbent paper which is in contact with the aluminized mylar sensor strips. When the sensor unit is attached to the undergarment, the sensor strip unit is extended downward inside the undergarment to lay over the groin. The top side of the paper sheath surrounding the two aluminized mylar sensor strips has an adhesive which secures the strip to the undergarment. The adhesive is exposed by peeling a paper backing from the sensor strip unit.

When the subject urinates or defecates, the released fluid is absorbed by the inner portion of the sensor strip unit through the holes of the outer apertured paper. The absorbed fluid contacts the aluminized mylar sensor strips encased within the paper sheath, and creates a "bridge" between the two conductive strips so that the electrolytes in the fluid complete an electrical circuit with those strips. Once the circuit is completed by the fluid, the alarm is activated to indicate that the person wearing the device has either urinated or defecated. (The vibrator alarm for DryTime® for Bladder Control Silent is a model 7CE-1701 manufactured by Namiki; this Namiki vibrator is also used as the alarm for Motorola electronic pagers.)

At the same time the circuit is completed, a transistor in the alarm unit switches the current to another circuit, thereafter bypassing the aluminized mylar sensor strips. This ensures that the alarm will remain activated once fluid has been detected, regardless of any movements by the subject that might otherwise break the initial circuit created by the fluid bridge between the mylar sensor strips. The activation of the transistor also ensures that current no longer flows through the aluminized mylar sensor strips.

INTENDED USE

The proposed device, DryTime® for Bladder Control Silent, is a daytime enuresis alarm that may be used by an ambulatory adult to assist the control of incontinence. It is designed and used in a manner consistent with the predicate device (i.e., the emission of bodily fluids is detected when those fluids complete an electrical circuit in a sensor device and thereby set off an electronic alarm).

The target population of DryTime® for Bladder Control Silent is ambulatory adults; the target population of DryTime® for Potty Training is toddlers.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICES

Similarities with Predicate Devices

DryTime® for Bladder Control Silent is very similar to the predicate device, DryTime® for Potty Training. Both devices are enuresis alarms; both are intended to be used to assist the wearer to detect excretion during the daytime by setting off an electronic alarm when excretion has occurred. Aside from the necessary changes in labeling, both devices are practically identical in appearance and function; both devices are comprised of the same sensor strip unit, Sense'R Strip®, the identical attachment materials, and an electronic alarm unit of similar circuitry, encased in a polystyrene container of identical size and material, with a label made of the same polyester film.

The instructions for placement of the alarm unit and the sensor strip unit, Sense'R Strip®, are identical for both devices. The electrical connection of the sensor strip to the alarm unit is also identical, and, in both devices, the alarm clips to the waistband of the undergarment using an identical soft vinyl strap and metal clip. While the predicate device, DryTime® for Potty Training, is designed with an audio alarm rather than a silent vibrator, both of the devices are designed to utilize an electronic alarm to signal that excretion has occurred. The alarm unit for each of the devices is powered by a 12 volt battery. Furthermore, in both DryTime® for Bladder Control Silent and DryTime® for Potty Training, the alarm unit circuitry includes a transistor which switches the current to a separate circuit at the time the alarm is activated, thereafter bypassing the aluminumized mylar sensor strips. This design ensures that the alarm will remain activated once fluid has been detected, regardless of any movements by the subject that might otherwise break the initial circuit created by the fluid bridge between the mylar sensor strips.

Differences from Predicate Device

There is only one major difference between the design of DryTime® for Bladder Control Silent and that of the predicate device, DryTime® for Potty Training: the alarm unit for DryTime® for Bladder Control Silent is a self-contained, battery operated, silent vibrator alarm, while the alarm unit for DryTime® for Potty Training is a self-contained, battery operated, buzzer audio alarm, with a small hole drilled into the alarm case to assist the sound to emanate. However, the design and operation of the circuitry are essentially the same for both devices.

The change in design was made to accommodate the change in target population; DryTime® for Bladder Control Silent is intended to assist an adult with incontinence control, while DryTime® for Potty Training is intended to assist in toilet training a child.

The minor change in design from the audio alarm of the predicate device, DryTime® for Potty Training, to the silent alarm of DryTime® for Bladder Control Silent, coupled with the change in target population from toddlers to ambulatory adults, raise no new questions of safety and efficacy.

BRIEF DISCUSSION OF NONCLINICAL TESTS

Because of the strong similarity between DryTime® for Bladder Control Silent and the predicate device, there has been no nonclinical testing of DryTime® for Bladder Control Silent to demonstrate safety and effectiveness.

BRIEF DISCUSSION OF CLINICAL TESTS

Because of the strong similarity between DryTime® for Bladder Control Silent and the predicate device, the determination of substantial equivalence does not include an assessment of performance data, and there has been no clinical testing of DryTime® for Bladder Control Silent to demonstrate safety and effectiveness.

CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS

Because of the strong similarity between DryTime® for Bladder Control Silent and the predicate device, no new questions of safety and efficacy are raised.

OTHER INFORMATION

No other information has been requested by FDA at this time.