

K963906

DEC -2 1996

## 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K963906

### Submitted By:

George Bolukbas, President  
Safety International Corp.  
160 Lyman Rd.  
Casselberry, FL 32707  
Tel (407) 830-0888  
Fax (407) 830-4988

Date Prepared: September 26, 1996

### Device Name

**Proprietary Name: Patient Restraints**

**Common Name: Belts**

**Classification Name: Protective Restraints (880.6760)**

### Substantial Equivalence Claim

Safety International Corp. Belts are similar in indications, design and features to various Protective Restraints that FDA has found to be substantially equivalent to the pre-amendment devices. The following are some such devices:

<b>Manufacturer</b>	<b>Product</b>	<b>510(k) Number</b>
Abco	Restraint, Protective	K850470
Biomet	Restraint, Protective	K780232
Dowling Textile	Restraint, Protective	K760618
Maddak	Restraint, Protective	K812473
Medical Restraints	Restraints, Protective	K771629

### Device Description

The Safety International Corp.'s Patient Restraints are easy to use devices which are used to secure patients to a ambulance cot, backboard, stretcher or wheelchairs. The belts utilize 2 inch wide, 2 piece nylon web with quick release automatic push button buckle. Auto chrome plated metal push button buckle provides positive closure and resists rust and corrosion. Buckle end is sewn and the adjusted end provides adjustment on the size of the restraints for the patient by pulling the open end of the restraint and adjusting to the

desired size. The belts are available in black, orange, burgundy, blue, red and yellow. The material used for the web is either nylon or polypropylene and has been in use with no adverse effects.

**Intended Use**

The Safety International Corp. Restraint Belt is designed to effectively secure the patient on a ambulance cot, backboard, stretcher or wheelchairs. They are also used for application as wrist or ankle restraints in conjunction with the patient restraints already on the equipment on which the patient is being carried.

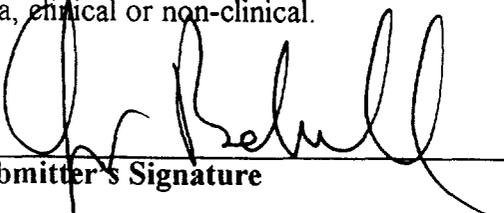
**Biocompatibility**

The material used for the web is either nylon or polypropylene and has been in use with no adverse effects. The same materials are used in the above mentioned substantially equivalent products.

**Substantial Equivalence Comparison**

	<b>Safety International Corp.</b>	<b>Morrison Medical Products</b>
Indication	Secure the patient on a ambulance cot, backboard, stretcher or wheelchairs.	Secure the patient on a ambulance cot, backboard, stretcher or wheelchairs.
Mode Of Operation	Strap with male connector on one end and female on the other lock together.	Strap with male connector on one end and female on the other lock together.
Material	Nylon webbing.	Nylon webbing.
Sterility	Nonsterile/reusable	Nonsterile/reusable

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.

  
 \_\_\_\_\_  
 Submitter's Signature

11/22/96  
 \_\_\_\_\_  
 Date