

JAN 28 1997

K963067

**GAYMAR®**

GAYMAR INDUSTRIES, INC.

**Premarket Notification [510(K)] Summary**

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**Date Summary Prepared:** July 26, 1996

**Device Name:** Sof.Press EPC 51 System

**Common Name:** Pneumatic Sequential Pump

**Classification Name:** Compressible Limb Sleeve per 21 CFR, Section 870.5800

**Predicate Device:** Jobst Extremity Pump System 7500 and Huntleigh Flowpress AC300

**Intended Use of Device:**

To aid in the reduction and management of peripheral edema such as lymphedema and ulceration associated with vascular insufficiency.

**Description:**

The Sof.Press EPC 51 System is an external pneumatic compression device that consists of a pump, an inflatable three cell sleeve, and connection tubing. Each cell of the sleeve is inflated sequentially with the highest pressure applied distally and with successively lesser pressures applied proximally.

**Substantial Equivalence:**

The following tables, Sof.Press Product Comparison Chart and the Safety Summary Chart, summarize the technological characteristics and the nonclinical performance data upon which the substantial equivalence submission was made to the Food and Drug Administration.

## SAFETY SUMMARY CHART

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	<b><u>Sof.Press</u></b>	<b><u>Jobst 7500</u></b>	<b><u>HNE 300</u></b>
<b>Biocompatibility</b>			
Primary skin irritation	pass	unknown	unknown
Delayed contact sensitization	pass	unknown	unknown
Cytotoxicity	pass	unknown	unknown
<b>Flammability</b>	pass	unknown	unknown
<b>UL Approvals</b>	UL 544	personal health care appliance UL 1431	UL 544
<b>Pressure Relief Valve</b>	yes	yes	no

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