

K961085

DeRoyal Industries, Inc.
DEROYAL INDUSTRIES, INC., MULTIDEX® PLUS GEL

MAY 21 1996

510(k) Summary

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**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
 UPON WHICH
 AN EQUIVALENCE DETERMINATION COULD BE BASED**

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc. **TELEPHONE:** (423) 938-7828
ADDRESS: 200 DeBusk Lane **CONTACT:** Debra F. Manning
ADDRESS: Powell, TN 37849 **DATE OF PREPARATION:** May 2, 1996

DEVICE NAMES

NAME: DeRoyal Industries, Inc., Multidex® Plus Gel
COMMON/USUAL NAME: Multidex® Plus Gel
CLASSIFICATION NAME (if known): Unclassified

PREDICATE OR LEGALLY MARKETED DEVICES

DeRoyal Industries, Inc., Multidex® Gel
 Lange, Multidex® Plus Powder

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Multidex® Plus Gel is the same as Multidex® Plus Powder formulated into a gel; therefore, it functions in the same manner as Multidex® Plus Powder. Like the powder, it is used in cases of chronic, non-healing wounds, ulcers, and over burns as a protective film. Like predicate devices, the gel is used to cover and protect wounds and to provide a moist environment conducive to healing. The basic scientific concepts that form the basis for the device is also like others in that the gel protects against wound dehydration and controls wound odors while decreasing the amount of purulent exudate.

Device Design/Materials Used/Physical Properties: The proposed DeRoyal Industries, Inc. Multidex® Plus Gel includes the same materials as Multidex® Plus Powder. The concept of use is that it can be easily applied to a wound or burn difficult to cover with the powder.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Multidex® Plus Gel is indicated for use for chronic, non-healing wounds, ulcers, and over burns to provide a protective film and a moist wound environment conducive to healing.

TECHNOLOGICAL COMPARISON WITH MULTIDEX® PLUS POWDER

Characteristics	Multidex® Plus Powder	Multidex® Plus Gel	Rationale
Form	Powder	Gel	The gel allows easier application to difficult to reach areas. Also, see explanation below.

The combination of glycerin with Multidex® Plus Powder allows a more soluble, elastic, plastic and flexible dressing that mixes better with wound and ulcer fluids.

Glycerin has been known since 600 AD, but was not chemically defined until 1741 by Scheele. It is a non-toxic, non-antigenic, non-allergic substance that is not rejected by human tissues and does not produce inflammatory responses or scarring reactions.

The Merck Manual (11th ed., 1988) lists the properties of glycerin including its use as a solvent, humectant, plasticizer, and emollient. Glycerin is also used in the fermentation of nutrients, in production of antibiotics, and in the chemical and pharmaceutical industries. It is also found in all human tissues either in pure form or in combination with other substances.

Additionally, as previously indicated, glycerin is used by other manufacturers of gel devices, including Southwest Technologies, in their Elasto-gel.