K964016

510(k) SUMMARY

DEC 31 1996

TIELLE* Hydropolymer Foam Dressing

1. **DATE PREPARED**

December 24, 1996

2. **SUBMITTER**

Johnson & Johnson Medical, Inc.
2500 Arbrook Boulevard, P.O. Box 90130
Arlington, Texas 76004-3130

3. **CONTACT**

Ralph H. Larsen., (817)784-4993
Sr. Project Manager, Regulatory Affairs

4 **NAME OF THE MEDICAL DEVICE**

Classification name:	Dressing, wound
Common/usual name:	Topical wound dressing
Proprietary name:	TIELLE* Hydropolymer Foam Dressing

5. **DEVICE CLASSIFICATION**

Classification for topical wound dressings has not yet been finalized by the Division of Surgical and Rehabilitation Devices. These devices are classified into Class I (General Controls).

6. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

TIELLE* Hydropolymer Foam Dressing is substantially equivalent and identical in function to Allevyn Hydrophilic Polyurethane Dressing marketed by Smith & Nephew.

7. **INDICATIONS FOR USE**

TIELLE Dressing is indicated for the management of both chronic and superficial, moderate to heavily exudating wounds, including the following:
Pressure sores (all stages)
Venous ulcers
Skin tears
Second degree burns
Donor and graft sites
Acute wounds healing by secondary or primary intention
Surgically debrided wounds

8. **PHYSICAL DESCRIPTION**

TIELLE* Hydropolymer Foam Dressing is made from a hydrophilic polyurethane polymer.

9. **BIOCOMPATIBILITY**

K964016

Safety tests demonstrate that TIELLE* Hydropolymer Foam Dressing is non-sensitizing, and non-irritating and suitable for its intended use.