

K970457

510(K) SUMMARY
(as required by 807.92(c))

MAY - 8 1997

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
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Contact Person: Ed Ransom

Date of Summary: February 3, 1997

Trade Name: Dukal ABD Combine pad

Classification Name: Dressing

Predicate Device: Hermitage Combine II Dressing

Device Description/

Comparison:

Material	Dukal	Hermitage Hospital
Thickness	47 mil	same
Delnet Fracture	5lb/in	same
T-Peel	700 lb/in	same
Absorptive Capacity	38 oz/yd ²	same
MD Tensile	6lb/in	same
Basis weight	5.0 oz/yd ²	same
Intended Use	The Dukal Sterile, ABD Combine pad is used as a topical dressing to cover a wound or operative site while providing absorbency.	same

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