

DEC 12 1996

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

12963689

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
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Date of Summary: September 13, 1996

Trade Name: Recover® Instant Heat Therapy Pack

Classification Name: Pack, Hot, Disposable

Predicate Device: Prism Technologies Instant Warm Gel

**Device Description/
Comparison:** Food Grade Sodium Acetate and water with a
stainless steel catalytic disc sealed in a nylon bag.
Provides heat to 112°F.

	Proposed Device	Marketed Device
	Florida Medical Industries	Prism Technologies
Solution	Food-grade sodium acetate and water	Food-grade sodium acetate, gel and water
Disc	Stainless Steel Catalytic disk	Stainless Steel disc
Temp.	112°	112°

Intended Use: The Recover® Instant Heat Therapy Pack is intended for use with conditions that indicate the use of heat therapy.