

K971045

510(k) Basis® Flexible Tip Digital Thermometer
PolyMedica Industries, Inc.

MAY - 2 1997

510(k) Summary

Proprietary Name: Basis® Flexible Tip Digital Thermometer
Common Name: Digital Thermometer with Flexible Tip
Classification: Class II
Submitter Details: PolyMedica Industries, Inc.
581 Conference Place
Golden, CO 80401
Tel: (303)271-0300
Fax: (303)271-0163
Contact: Ms. Susan Collins

The Basis® Flexible Tip Digital Thermometer is a clinical thermometer intended for the determination of oral, rectal and axillary body temperature determination in humans.

In terms of physical requirements and operating parameters, the thermometer conforms to ASTM E1112, "Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature".

Basis® Flexible Tip Digital Thermometer is substantially equivalent to PolyMedica Industries, Inc's Basis® Digital Thermometer and the Becton Dickinson Flexible™ Digital Thermometer.