

K962497

OCT - 8 1996



September 23, 1996

Food & Drug Administration
Center for Devices and Radiological Health
Document Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

510(k) #: K962497
Received: 26-JUN-96
Product: Q-TIPS®, FAICHNEY®,
& PRIVATE LABEL
CLINICAL ELECTRONIC
THERMOMETER

510(k) SUMMARY

Name of Applicant: Faichney Medical Company,
a division of Conopco, Inc.

Contact Person: M. James Davis
General Manager
Faichney Medical Company
17159 Surrey View Drive
Chesterfield, MO 63005

Telephone: (314) 530-0077

Facsimile: (314) 530-9948

Device Identification

Trade Name: Q-tips®, Faichney®, Private Label

Common Name: Clinical Electronic Thermometer

Establishment
Registration Number: 1933255

Classification: Class II (21 CFR 880.2910)

Panel: Panel 80, General Hospital and Personal Use Device Section of
the General Medical Devices Panel

Procodel: FLL -- thermometer, electronic, clinical

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ATTACHMENT #1

**Performance
Standard:**

Performance standards have not been adopted by the FDA for clinical electronic thermometers. This thermometer is compliant with the standards established by the American Society for Testing and Materials (ASTM), Designation E1112-86. The disposable probe cover for this thermometer is compliant with standards established by ASTM, Designation E1104-86. The specification is under the jurisdiction of ASTM Committee E-20 on Temperature Measurement and the direct responsibility of the ASTM Subcommittee E20.80 on Medical Thermometry.

Comparable Device

This device is substantially equivalent to other digital thermometers in commercial distribution such as the Becton-Dickinson Digital Fever Thermometer. The 510(k) Document Control Number for the Becton-Dickinson Digital Fever Thermometer. is K852954.

Description of Device and Intended Use

The Faichney Medical Company and Becton-dickinson digital thermometers are intended for measuring body temperature using oral, rectal, or axillary sites. There are no technological differences between these thermometers. The Becton-Dickinson digital thermometer is a Class II, Panel code 80 FLL, device approved for commercial market.

Summary of Bench Data

Laboratory tests of the Faichney digital fever thermometer were conducted by an independent testing house.

Regarding "Accuracy" the temperature Range, Mean & Standard Deviation of the digital thermometer is better than that of the mercury-in-glass thermometer (Reference Table #1 and Table #2, Attachment #6a). The investigator concluded that..."it may be stated with a confidence interval of 89 percent that the accuracy of the electronic thermometers (both with and without probe covers) is within 0.1°F of the accuracy of the glass stem product or better at every range but the 96.4°F to 98.0°F."

Regarding "Response Time", as expected, there is a slight increase in the time required for the digital thermometer to reach Peak Temperature. The investigator concluded that..."When tested without probe covers, the product averaged 26 seconds to register peak temperature. The same units, when tested with probe covers, averaged 28 seconds to register peak temperature.

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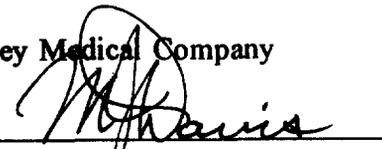
Conclusions Regarding Safety and Effectiveness

The Faichney Medical Company digital thermometer, which is substantially equivalent to the Becton-Dickinson digital thermometer, is safe and effective for its intended use.

Sincerely,

Faichney Medical Company

By: _____

A handwritten signature in black ink, appearing to read "M. James Davis", is written over a horizontal line. The signature is cursive and somewhat stylized.

M. James Davis, General Manager

Enclosures