

RADIOMETER AMERICA INC.

Exhibit IX

MEDICAL DIVISION

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K962158

OCT 29 1996

SUBJECT: 510(k) SUMMARY**FROM:** Donald L. Baker
Director of Marketing and Regulatory Affairs
Radiometer America, Inc.
810 Sharon Drive
Westlake, Ohio 44145
(216)871-8900, Ext. 287 or 1-800-736-0600
Fax (216)871-8117**DATE:** May 16, 1996**PRODUCT:** Trade Name -PICO
Common Name - PICO Arterial Blood Sampler
Classification Name - Kit, Sampling, Arterial Blood**PREDICATE****DEVICE:** Qualistick, Pulsator, B-D, QS90 Smooth'E™**PRODUCT****DESCRIPTION:** Preheparinized, electrolyte balanced, arterial blood sampler for pH, blood gas, oximetry, electrolyte and metabolite analyses. Available in multiple sizes and product versions.**INTENDED****USE:** Arterial blood sampler for pH, blood gas, oximetry, electrolyte and metabolite analyses.**TECHNOLOGICAL
CHARACTERISTICS
VERSUS PREDICATE
DEVICE:**

PICO product line is technologically similar to the Smooth'E™ product line.

SUBSTANTIAL**EQUIVALENCE:** The PICO product line is substantially equivalent in features, intended use, and characteristics to the current Smooth'E™ product line (K896514) marketed by Radiometer America Inc. The significant difference from Smooth'E™ to the new PICO design is the addition of metabolite and oximetry to the product labeling.