

RADIOMETER AMERICA INC.

K961355

Exhibit VII

MEDICAL DIVISION

811 SHARON DRIVE, WESTLAKE, OHIO 44145-1688
800-738-0600, 216-871-8900
FAX 216-882-8117

JUN 14 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, Ext287 or 1-800-736-0600
Fax (216)871-8117

DATE: April 1, 1996

PRODUCT: Trade Name - Multicheck™
Common Name - Quality Control
Classification Name - Controls for Blood Gas (assayed and unassayed)

PREDICATE

DEVICE: Multicheck™

PRODUCT

DESCRIPTION: Multicheck™ with metabolite is a four level quality control system consisting of part numbers S5530, S5540, S5550, and S5560. Each level consists of 30 ampoules per box, 2 mL solution per ampoule.

INTENDED

USE: Multicheck™ with metabolite is intended for checking the precision and accuracy of Radiometer and non-Radiometer analyzers for pH/Blood Gases, Oximetry, Electrolytes, and Glucose and Lactate.

TECHNOLOGICAL CHARACTERISTICS

VERSUS PREDICATE

DEVICE: Multicheck™ with metabolite is technologically similar to Multicheck™ with glucose.

SUBSTANTIAL

EQUIVALENCE: Multicheck™ with metabolite is substantially equivalent in features and characteristics to the current Multicheck (K952725) marketed by Radiometer America Inc. The only difference is the addition of the lactate analyte.