

OCT 24 1996

# RADIOMETER AMERICA INC.

EXHIBIT VI

MEDICAL DIVISION

811 SHARON DRIVE, WESTLAKE, OHIO 44146-1688  
800-736-0800, 216-871-8900  
FAX 216-892-8117

K962334

**SUBJECT:** 510(k) SUMMARY

21

**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:** June 3, 1996

**PRODUCT:** Trade Name - EML105  
Common Name - Electrolyte Metabolite Analyzer  
Classification Name - Electrolyte Ion Specific

## PREDICATE

**DEVICE:** EML105 and YSI 2300

## PRODUCT

**DESCRIPTION:** EML105 is an automated electrolyte metabolite analyzer that is 40 cm x 35 cm x 40 cm (WHD) and weighs 22 kg. It measures on whole blood and urine in approximately 54 seconds.

## INTENDED

**USE:** EML105 is a stand alone, electrolyte metabolite analyzer that measures Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>, Cl<sup>-</sup>, glucose and lactate on whole blood and urine. It can be interfaced with an ABL analyzer 500/510/520 to become an ABL System 605/615/625 for the measurement of pH/Blood gases, electrolytes, metabolites and co-oximetry.

## TECHNOLOGICAL CHARACTERISTICS

### VERSUS PREDICATE

**DEVICE:** EML105 (with lactate) is technologically similar to the current version EML105.

## SUBSTANTIAL

**EQUIVALENCE:** EML105 with lactate is substantially equivalent in features and characteristics to the current version EML105 marketed by Radiometer America Inc. (K952621). The only difference is the addition of the lactate analyte. Like the current version of EML105, the EML105 with lactate can be interfaced with an ABL analyzer to form an ABL System 605, 615 or 625. The predicate device for the lactate analyte is YSI 2300.