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Attachment 7

NOV -5 1996

510(K) SUMMARY

ANTHOS PHACTS VERSION MICROPLATE READER

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Anthos PhACTS Version Microplate Reader

Submitter's Name, Address, Telephone Number, And Contact Person

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Name of the Device

Anthos PhACTS Version Microplate Reader

Common or Usual Name

Microplate reader

Predicate Devices

(1) Anthos 2001 Microplate Reader (K894270);

(2) Anthos ht2 Microplate Reader (K931907);

(3) Anthos 2010 Microplate Reader (K955077);

Intended Use

The Anthos PhACTS 2010 Microplate Reader is intended to be used as a general purpose microplate photometer for clinical use.

Principles of Operation

The Anthos PhACTS 2010, 2001 and its predicate devices all share the same principle of operation. Briefly, each device provides a light source which is focused to provide illumination of wells in a microtiter plate. A corresponding silicon-photodiodes measures the amount of light absorbed by the sample as the light passes through the microplate well. The respective well absorbance measurements is used by the data reduction software to yield a specific well absorbance value which in turn can yield a qualitative or quantitative assay result.. Thus, the Anthos PhACTS 2010, 2001 and its predicate devices have similar principles of operation.

Technical Characteristics

The Anthos PhACTS 2010 and 2001 microplate reader and the predicate readers employ an automatic transport mechanism to bring the individual microplate wells into position for reading. The devices all employ Tungsten halogen lamp as the light source. All three devices use silicon-photodiodes to measure the light absorbance.

Summary of the Basis for the Finding of Substantial Equivalence

The Anthos PhACTS version readers use the same technique for the measurement of light absorbance and are equivalent to the predicate devices for its intended use. There is no substantial difference between the Anthos PhACTS version readers and their predicate devices in performance or technical characteristics. The Anthos PhACTS readers have the same intended use, indications for use, and the same principles of operation for its indications for use as the predicate devices.