This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DCRND

Electrocardiograph (ECG) Lead Switching Adaptor

Version 1.0

This Document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices
Anesthesiology and Defibrillator Devices Group

Document issued on:

FEB 11 1997

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to Curtis Truesdale, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. For questions regarding the use or interpretation of this guidance, contact Curtis Truesdale at (301) 443-8609.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Lead Switching Adaptor

Version 1.0

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Anesthesiology and Respiratory Devices Group
Division of Cardiovascular, Respiratory and Neurological Devices
Office of Device Evaluation

Document Issued on:
2/11/97

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to Curtis Truesdale, Center for Devices and Radiological Health, 9200 Corporate Boulevard (HFZ-450), Rockville, MD 20850. For questions regarding the use or interpretation of this guidance, contact Curtis Truesdale at (301) 443-8609.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Guidance Document

Device: ECG lead switching adaptor

I. Device Description

Common name:	Electrocardiograph lead switching adaptor
Class:	II
Classification panel:	74
Product code:	DRW
Regulation number:	870.2350

An electrocardiograph lead switching adaptor is a passive switching device to which surface electrocardiograph limb and chest leads may be attached.

II. Indication for use

The device is intended to be used to connect various combinations of limb and chest leads to the output terminals in order to create lead combinations such as the 3-lead, 6-lead, and 12-lead ECG combinations. It is intended for surface ECG only.

III. Preclinical Data

Lead weighting factors employed in ECG lead switching adaptors shall be implemented according to those specified in table 3 of the Association for the Advancement of Medical Instrumentation (AAMI) EC11-1994 standard. Testing of the lead weighting factors should be provided showing evidence of accuracy within $\pm$ 5 percent tolerance. Lead nomenclature, patient electrode connection definitions, and color code should also conform with table 1 and 3 of AAMI EC11-1994 standard.

IV. Clinical Data

Clinical data is not applicable.

V. Software/Hardware Information

A circuit diagram and a description of the hardware design should be provided.

VI. Examples of Predicate Devices

Company: Physio-Control Corporation
Product: Limb Lead Selector
510(k): K761210

VII. Sterilization Information

Sterilization information is not applicable.

VIII. Labeling Information

The following labeling information should be provided:

I) a concise statement of intended use;
ii) cautions and warnings regarding the proper use of the device;
iii) instructions for use;
iv) patient electrode connection nomenclature and color code conforming with table 1 of AAMI EC11-1994;
v) identification of panel controls and switches; and,
vi) performance specifications.

Checklist for ECG Lead Switching Adaptor

The following items should be provided by the applicant:

1) Evidence showing that lead weighting factors are implemented according to those specified in table 3 of AAMI EC11-1994 standard.

2) Testing of the weighting factors showing evidence of accuracy within ±5 percent tolerance.

3) Labeling information consisting of the following items:

   a. a concise statement of intended use;
   b. cautions and warnings regarding the proper use of the device;
   c. instructions for use;
   d. patient electrode connection nomenclature and color code conforming with table 1 of AAMI EC11-1994;
   e. identification of panel controls and switches; and,
   f. performance specifications.

4) A circuit diagram and a description of the hardware.