

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.

GUIDELINES FOR EVALUATION OF FETAL CLIP ELECTRODES

Adopted by the OB/GYN Classification Panel

March 8, 1977

Prepared by the Fetal Monitoring Device Subcommittee

Subcommittee Members

John T. Queenan, M.D. (Subcommittee Chairman)
Lyra Gillette, M.D.
Charlotte Kerr, M.D.

Consultants

Peter A.M. Auld, M.D.
Tom P Barden, M.D.
Roger K. Freeman, M.D.
Neil K. Kochenour, M.D.

Guidelines for Evaluation of Fetal Clip Electrode

INTRODUCTION

These general guidelines for a product development protocol for fetal clip electrodes have been prepared by the Fetal Monitoring Device Subcommittee of the Obstetrics and Gynecology Device Classification Panel, Bureau of Medical Devices and Diagnostic Products, Food and Drug Administration.

The voting members are:

John T. Queenan, M.D. (Subcommittee Chairman)
Lyra Gillette, M.D.
Charlotte Kerr, M.D.

The consultants are:

Peter A.M. Auld, M.D.
Tom P Barden, M.D.
Roger K. Freeman, M.D.
Neil K. Kochenour, M.D.

These guidelines are intended as overall guides to the investigation of fetal clip electrodes. The place for specifics is in the individual product development protocols. Specific protocol will be evaluated and approved of their own merits.

OBJECTIVE

The objective of preclinical and clinical investigation is to assess the relative safety of the fetal clip electrodes, their effectiveness in achieving fetal monitoring, the risks or undesirable effects and the relative relationship of these assessments.

I. Preclinical Guidelines (Phase I)

A. Description (design of device)

The applicant should provide detailed drawings and descriptions of the device and its accessories (if any). The physical characteristics of the device should be indicated and the rationale for the design should be stated in the light of the relevant literature.

Design characteristics to be indicated:

1. Application - Should allow a person trained in fetal monitoring to apply the device with reasonable facility. Method of introduction should minimize contamination.

2. Retention - Should be adequate to keep the device in place for the duration of labor.
3. Tissue Damage - Device should operate with minimal tissue damage. Depth of penetration should be minimal to afford application and retention.
4. Removal - Should be capable of being removed with facility prior to delivery without further tissue injury.
5. Sterility - Should meet FDA sterility standards.
6. Biocompatibility - Proper biocompatibility studies should be done.

II. Clinical Guidelines

Prior to clinical testing, it must be documented that appropriate biocompatibility studies have been carried out.

Investigation of this nature are to be conducted in such a way that the participating subjects or patients are exposed to the least possible risk consistent with the anticipated benefit.

The patients must be fully informed of:

1. the benefits and risks of other electrodes
2. the risks as well as benefits of fetal clip electrodes in general and any specific risk of the fetal clip electrode being investigated.
3. an experimental device that is to be used in a patient.

Clinical Study

It should be a comparative study. An investigator must be generally knowledgeable about fetal electrodes for monitoring and experienced in the technique of using fetal electrodes. The analysis of the study should be statistically valid.

The data needed to be collected are the following:

1. maternal infection
2. tissue damage
3. fetal infection

4. hemorrhage
5. duration of ruptured membranes
6. duration of labor
7. mode of delivery
8. total neonatal morbidity
9. total maternal morbidity