Indications for Use Statement

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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.

February 6, 1996

Dear Premarket Notification Submitter:

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration is announcing a change in the way we will handle the premarket notifications (510(k)s). CDRH will include the indications for use in the clearance letters for devices found to be substantially equivalent to a legally marketed predicate device. This change will apply to original 510(k)s received after January 1, 1996 (all 510(k)s with numbers beginning with K96). We believe this practice will reduce confusion between the agency and 510(k) submitters on which indications for use have been cleared.

To maintain a streamlined process, we are asking each 510(k) submitter to clearly identify the indications for use for which a substantially equivalent determination is sought using a separate sheet of paper. We are also asking submitters to include the device name and 510(k) number (if known) on this sheet. To accurately reflect the 510(k) submitter's stated indications for use, as mutually agreed upon, we will enclose this same sheet to the outgoing substantially equivalent letter. If modifications or deletions are made to the indications as submitted, these will be negotiated with the submitter and the cleared indications will be clearly delineated. We have enclosed a recommended format for this sheet with every outgoing acknowledgement letter for 510(k)s received since January 1, 1996.

We do not view this as a new requirement for 510(k) submitters. We have always required that the indications for use be included in every 510(k) submission. This procedural change simply facilitates the submitter's and agency's identification of the specific indications for use that are cleared.

We appreciate your continued cooperation and support in making our premarket review programs more efficient.

Sincerely yours,

Philip J. Phillips
Deputy Director
Office of Device Evaluation
Center for Devices and
Radiological Health

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