

Re: Panel slides for General indications.

Memo Date: June 13, 2000

The FDA is requesting comments and advice for a proposed change to the
Implanted Cardioverter Defibrillator guidance.

FDA Presentation
Mike Bazaral

The proposed intended use statement is:

The (implantable defibrillator) is intended to provide (ventricular antitachycardia pacing and) ventricular defibrillation, for automated treatment of life-threatening ventricular arrhythmias.

A functional intended use statement.

Does not specify which patients are at risk of life-threatening ventricular arrhythmias.

The intended use statement now used for ICDs is:

The implantable defibrillator (ICD) is indicated for use in patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have experienced one of the following situations:

- 1) Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia;
- 2) or recurrent poorly tolerated sustained ventricular tachycardia.

1) Survival of at least one episode of cardiac arrest (manifested by loss of consciousness) due to a ventricular tachyarrhythmia;

2) or recurrent poorly tolerated sustained ventricular tachycardia.

a) These indications are the entry criteria for the studies to demonstrate effectiveness and safety of the ICDs, and were chosen to assure a high prevalence of life-threatening ventricular arrhythmias.

b) The indications as stated give the impression that the FDA-approved labeling defines the population at risk, although that was not the purpose of the studies.

One manufacturer's (Guidant) current intended use does include an additional patient population:

- 1) Prior myocardial infarction
- 2) and left ventricular ejection fraction of 35% or less,
- 3) and a documented episode of nonsustained ventricular tachycardia
- 4) with an inducible tachyarrhythmia.
- 5) Patients suppressible with IV procainamide or an equivalent antiarrhythmic have not been studied.

The indication is based on the MADIT trial that showed improved survival for this population treated with this brand of defibrillator (Moss et al, 1996)

The proposed functional intended use statement:

".... for automated treatment of life-threatening ventricular arrhythmias"

is a recognition that although:

- 1) the data submitted to the FDA for ICDs are from trials designed to evaluate safety and effectiveness of the ICDs in a population known to be at risk,
- 2) single-manufacturer ICD trial data submitted to the FDA generally do not address the question of which patients are at risk of ventricular arrhythmias.

The proposed intended use statement relies on implicit assumptions:

- 1) Approved ICDs can treat ventricular arrhythmias.
- 2) Detection and defibrillation by an ICD will not be affected by the differences among cardiomyopathies.
- 3) Differences among patients are minimized by individualized settings.
- 4) Information on the diseases or conditions that cause life-threatening ventricular arrhythmias is available to the physician from sources other than the device labeling.

Functional intended use statements have been applied to other devices:

1) artificial heart valves are indicated for:

"The replacement of malfunctioning native or prosthetic (aortic) or (mitral) heart valve."

2) coronary balloon angioplasty catheters are indicated for:

" balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion"

- 1) The functional intended use statement would be incorporated into the ICD guidance for new ICDs.
- 2) The guidance for new ICDs would state that clinical trials information would appear in the label in the summary of clinical data, but only when the clinical data result from the study of one manufacturer's device.
- 3) The functional intended use statement would be available as an optional alternative for currently approved ICDs.
- 4) Other device functions incorporated into the ICD, or unique ICD functions may have separate or additional intended use statements.