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.

PMA REVIEW STATISTICAL CHECKLIST

	Yes	No	Comment
I. Organizational and Administrative Elements including Table of Contents with volume and page numbers	___	___	_____
II. Summary of Safety and Effectiveness			
A. Indications for use	___	___	_____
B. Claims for the device	___	___	_____
C. Summary of studies	___	___	_____
III. Clinical Investigations			
A. Protocol			
1. included	___	___	_____
2. adhered to	___	___	_____
3. deviations described	___	___	_____
B. Patient Accountability			
1. patient inclusion/ exclusion criteria	___	___	_____
2. follow-up schedule	___	___	_____
3. study period completed	___	___	_____
4. all patients accounted for	___	___	_____
C. Description of Safety and Effectiveness Parameters			
1. safety	___	___	_____
2. effectiveness	___	___	_____
a. sensitivity	___	___	_____
b. specificity	___	___	_____
c. false positive	___	___	_____
d. false negative	___	___	_____
e. reproducibility	___	___	_____
f. repeatability	___	___	_____
g. stability	___	___	_____
D. Documentation of Statistical Analysis and Results			
1. control (comparison) group	___	___	_____
2. sample size justified	___	___	_____
3. hypothesis test stated	___	___	_____
4. potential of bias adequately evaluated			
a. randomization or blinding techniques	___	___	_____
b. descriptive and stratified analyses			
(1) patient demographics	___	___	_____
(2) investigator	___	___	_____
(3) site	___	___	_____
(4) surgical technique	___	___	_____
5. pooling of data justified	___	___	_____

(over)

6. statistical test given	___	___	_____
7. clear presentation of data	___	___	_____
8. statistical results stated	___	___	_____
9. statistical conclusions drawn from results	___	___	_____