

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

—	—	—
—	—	—
—	—	—
—	—	—