510(k) Elements List

510(k) Elements	Authority (21 CFR)	Included in Cover Sheet?
1. Device trade or proprietary name	807.87	yes
2. Device common or usual name or classification	807.87	yes
3. Establishment registration number (only applies if establishment is registered)	807.87	Firm no, Mfg. yes
4. Class in which the device has been put under section 513 of the act and, if known the appropriate panel; or if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.	807.87	yes
5. Action taken by the party required to register to comply with the requirements of the act under section 514 for special controls.	807.87	N/A
6. Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. (Blue Book Memo #G91-1)	807.87	yes
7. 510(k) summary or a 510(k) statement.	807.87 (h)	Summary
8. For class III only, a class III certification and a class III summary.	807.87 (i)	no
9. Photographs of the device.	807.87	yes
10. Engineering drawing of the device.	807.87	yes
11. Identification of the marketed device(s) to which equivalence is claimed including labeling and description of the device. Affiliated 510(k) numbers and product codes are voluntary in cover sheet.	807.87	yes
12. Statement of similarities and/or differences with marketed device(s).	807.87	yes
13. Data to show consequences and effects of a modified device.	807.87	N/A
14. Submitter's name and address.	807.87	yes
15. Contact person, telephone number and fax number.	807.87	yes
16. Representative/Consultant if applicable.	807.87	N/A
17. Table of Contents.	807.87	yes

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510(k) Elements	Authority (21 CFR)	Included in Cover Sheet?
18. Name and address of manufacturing/packaging/sterilization facilities. Registration number of each facility when one exists.	807.87	yes
19. Comparison table of the new device to the marketed device(s).	807.87	yes
20. Action taken to comply with voluntary standards.	807.87 FDA discretion	yes
21. Performance data (bench, animal, clinical).	807.87 FDA discretion	yes
22. Sterilization information (Blue Book Memo #K90-1).	807.87 FDA discretion	N/A
23. Software information (Blue Book Memo #K91-1).	807.87 FDA discretion	yes
24. Hardware information.	807.87 FDA discretion	yes
25. Information requested in specific guidance documents (if applicable for this device).	807.87 FDA discretion	yes
26. Kit Certification Statement (for kit submission only).	807.87 FDA discretion	N/A
27. Truthful and Accurate Statement.	807.87 (j)	yes