	Operation	Submit 510(k)	Register	List	COMPLY W/GMP
1.	Manufacture and distribute device	YES: 807.81(a)	YES 807.20	YES 807.20(a)	YES
2.	Contract manufacturer who commercially distributes device for specifications developer	NO: 807.81(a)	YES if domestic: 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
3a.	Contract manufacturer who meets the definition of finish-ed device manufacturer per 21 CFR 820.3(l), but does not commercially distribute device for specifications developer	NO	NO: 807.20(c)(1)	NO: 807.20(c)(1)	YES
3b.	Contract manufacturer who does not meet the definition of finished device manufacturer per 21 CFR 820.3(l) (e.g., component manufacturer, subassembler) but does not commercially distribute device for specifications developer	NO	NO: 807.20(c)(1)	NO: 807.20(c)(1)	NO
4	Manufacturer modifies device or new intended use and distribute	NO: preamble no. 17 & 18 FR 8/23/77 YES: 807.81(a)(3) with signif. change in device or use	YES 807.20(a)	YES 807.20(a)	YES
5	Distribute U.S. Made device: no specification initiation (domestic distributor)	NO: 807:85(b)	NO: 510(g)(4) of act, 807.20(c)(3)	NO	NO
6	Specification initiator and distribute only	YES: 807.81(a)	YES: 807.20(a)(1) preamble no. 5, FR 8-23-77	YES: 807.20(a)(1)	YES: 820.181, etc.
7	Specification consultant only; no distribution	NO	NO: preamble no, 5, FR 8-3-77	NO	NO
8	Relabeler or repacker: distribute under own name	NO: 807.85(b): no change to device or existing labeling	YES: 807.20(a)(3)	YES: 807.20(a)(3) preamble no. 7, FR 8-25-78	YES
9	Kit assembler using prelabeled & prepackaged devices only	NO: no change in device or existing labeling other than adding dist. name & address 807.81(a)(3)	YES: 807.20(a)	YES: 807.20(a)	NO
10	Kit assembler changes intended use (801.4) of prepackaged/prelabeled devices	YES: 807.81(a)	YES: 807.20(a)(2)	YES: 807.20(a)(2)	YES: 820.120, 820.130, etc.
11	Kit assembler changes prepackaged/prelabeled devices	NO: if no significant change to labeling or device: otherwise YES: 807.81(a)(3)(i)	YES: 807.20(a)(3)	YES: 807.20(a)(3)	YES
12	Manuf. Accessory, component and package & label for health purpose to end user.	YES: 807.81(a)	YES: 807.20(a)(5) preamble no. 77, FR 8-25-78	YES: 807.20(a)(5)	YES
13	Manuf. Components & dist. Only to finished device mfr.	NO: 807.81(a)	NO: 807.65(a)	NO	Use as guide: 820.1
14	Contract mfr. Of subassembly or component (see no. 12, accessory)	NO	NO	NO	Primary mfr. must see that GMP is met preamble no. 33, FR 7-21-78
15	Contract packager or labeler	NO	NO	NO	Primary mfr. must see that GMP is met preamble no. 33, FR 7-21-79
16	Contract sterilizer who commercially distributes device	NO	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES if domestic 807.20(a)(2), YES if foreign 807.40(a)	YES
17	Contract sterilizer who does not commercially distribute device	NO	NO: 807.20(c)(2)	NO: 807.20(c)(2)	YES
18	Manufacture custom device (domestic or foreign)	NO: 807.85(a)(1)&(2)	YES 807.20(a)(2)	YES 807.20(a)(2)	YES: also see 520(b); 520(f)
19	U.S. Establishment who manufactures for export only	NO	YES 807.20(a)(2)	YES 807.20(a)(2)	YES
20	Foreign manufacturers and all foreign establishments	YES: 807.81 foreign mfr. has primary responsibility, but may delegate to an init. Dist.	YES, 807.40(a)	YES 807.40(a)	YES
21	Initial distributor/importer of device	YES: 807.81(a) or 807.85(b) unless 510(k) has been filed by foreign manufacturer or another init. Dist	YES: 807.40(a)	NO: enforcement discretion used for 807.22(c)	YES: 807.3(d), 820.198, 820.100, 820.200, etc.
22	Installer-mfr.'s agent	NO	NO	NO	YES: 820.170
23	Installer-user	NO	NO	NO	NO: for x-ray see 1020.30(d) report
24	Device being investigated under ide	Exempt: 812.1(a)	NO	NO: 807.40(c)	Exempt per 812.1(a), except for Design Control per 820.30
25	Mfr. Buys manufacturing rights for device (see no. 4)	NO: preamble 18 FR 8-23-77 only if same type of manuf. equip. is used and no signif. change to device	YES: 807.20(a)(2) if not already registered	Send letter to FDA per 807.30(b)(5) & 807.26	YES
26	Reprocessor of single use device	YES	YES: 807.20	YES: 807.20	YES
27	Foreign exporter of device (device manufactured in foreign country)	YES: (original manufacturer's 510(k) maybe used)	YES: 807.40 (a)	YES: 807.40 (a)	