

| 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)                                        |                                                                   |