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FAQ No.:	38
FAQ:	Do Medical Device Manufacturers Have To Be Registered With The FDA?

Yes. Section 510 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 3507) requires that manufacturers and initial importers engaged in the manufacture, preparation, propagation, compounding, assemble, or processing of medical devices intended for human use and in commercial distribution register their establishments and list the devices they manufacture with the FDA. See 21CFR 807.20 for specific regulation.

Website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=807.20 for complete regulation

We hope that this answers your questions. If you have any further questions, please feel free to call Posey Customer Service at (800) 44-Posey or (800) 447-6739.