

Panel Questions
P030050
Dermik Laboratories SCULPTRA

1. 21 CFR 860.7(d)(1) states that there is a reasonable assurance that the device is safe when it can be determined that the probable benefits to health from use of the device for its intended uses, when accompanied by adequate instructions for use and warnings against unsafe use, outweigh any probable risks. Considering the data in the PMA, please comment on whether there is a reasonable assurance that the device is safe.
2. 21 CFR 860.7(e)(1) states that there is a reasonable assurance that a device is effective when it can be determined, based on valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will produce clinically significant results. Considering the data in the PMA, is there reasonable assurance that the device is effective?
3. Patients in the European studies (79) were followed-up for periods ranging from 24 weeks to 2 years, and those in the U.S. studies (200) were followed up to 2 years. If you agree that there is enough evidence in the PMA to support the safety and effectiveness of the device, do you feel that a post-approval study to assess the long term use of this device should be initiated, and if so, please advise FDA as to the type of data you feel should be collected, and the appropriate duration of follow-up.
4. A large volume of this device (up to 11cc. per treatment) is required to achieve an optimal cosmetic effect, and precise placement of the material in the correct dermal plane (deep dermis or subcuticular layer) is important. Please advise FDA whether a physician training program is indicated for those wishing to use this device, and if so, what type of training would be appropriate.