

Ombudsman's Summary of the Scientific Issues in Dispute

On November 15, 2000, the Office of Device Evaluation (ODE) in FDA's Center for Devices and Radiological Health, sent Lifecore Biomedical a not approvable letter regarding its Premarket Approval Application (PMA) P990015, as amended, for Intergel Adhesion Prevention Solution. The letter states that there is not sufficient information directly relating the performance of this device to its indication for use to demonstrate reasonable assurance of safety and effectiveness. The indication for use, as described in Lifecore's amendment to the PMA (Amendment 11), dated June 2, 2000, is for use as an intraperitoneal instillate for reduction of adhesion formation following gynecologic pelvic surgery. This amendment modified the indication for use that was proposed in the original PMA, which was for a general surgery indication. Lifecore disagrees with ODE's decision to issue the not approvable letter and the reasons for issuing it as enumerated in the letter. It is Lifecore's opinion that the existing scientific data provides reasonable assurance of safety and effectiveness. Specifically, Lifecore believes the PMA as amended should be approved because the available data shows that: a) there exists a statistically and clinically significant benefit in favor of Intergel Solution as compared to control (lactated Ringer's solution) in reducing adhesion formation following gynecologic pelvic surgery, and b) this benefit is achieved without exposing the patient to any unacceptable risks, including infection.

Thus, the Dispute Resolution Panel, to whom Lifecore has appealed the not approvable letter, will be charged to answer the following and make a recommendation to the Director of the Center for Devices and Radiological Health as to how this scientific dispute should be resolved:

Does the PMA as amended provide reasonable assurance of the safety and effectiveness of Intergel for its intended use as an intraperitoneal instillate for reduction of adhesion formation following gynecologic pelvic surgery?

In answering this question the Panel should determine:

1. Whether the statistically significant differences between Intergel Solution and control can be considered to be clinically significant?
2. Do the benefits of the product outweigh the potential risks, including any risk of infection?