

MEDICAL BIOCOMPATIBILITY TESTING

Biocompatibility testing of medical devices is essential to ensuring the safety of patients who use the device. Such tests determine the interaction of the medical device and the tissues and physiological systems of the patient. These tests are only a part of the total assessment necessary for evaluating the safety of a device. In order to grant approval of a medical device, the FDA requires biocompatibility and other tests to be done on the actual part. FDA does not grant approval on components of a device.

The table below lists the tests and results performed by independent testing organizations on behalf of Gentex Corporation. **These results provide medical device manufacturers the confidence that the Clearweld® material will not be a barrier in obtaining FDA approval of their device.** Additional information relating to such testing can be provided upon request.

| TEST | CLEARWELD® MATERIAL TESTED | RESULT |
|---|--|---------------------------------------|
| Cytotoxicity | Raw IR absorber | Nontoxic ¹ |
| | Coating applied to plastic — pre laser exposure | Nontoxic ² |
| | Coating applied to plastic — post laser exposure | Nontoxic ² |
| USP Systemic Toxicity | Coating applied to inert substrate — pre laser exposure | Meet the requirements of USP Class VI |
| | Coating applied to inert substrate — post laser exposure | Meet the requirements of USP Class VI |
| USP Intracutaneous Toxicity | Coating applied to inert substrate — pre laser exposure | Meet the requirements of USP Class VI |
| | Coating applied to inert substrate — post laser exposure | Meet the requirements of USP Class VI |
| USP Muscle Implantation | Coating applied to inert substrate — pre laser exposure | Meet the requirements of USP Class VI |
| | Coating applied to inert substrate — post laser exposure | Meet the requirements of USP Class VI |
| Extraction and Identification of Decomposition Products | Coating applied to inert substrate — post laser exposure; irradiated dye washed with methanol for extraction | No toxic byproducts were identified |

¹Cytotoxicity study using the Agarose Overlay Method

²Cytotoxicity study using the MEM Elution Method



CLEARWELD®

6 EMMA ST. • BINGHAMTON, NY 13905 • USA

P 607.296.4721 • F 607.729.3322 • E-MAIL CLEARWELD@CLEARWELD.COM