How Histology Can Help Injectable Medical Devices Validity

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Injectable medical devices respond to the definition of a long-term, invasive, surgical device since they are introduced invasively into the body and are intended to remain in place for several days to years. In order to be marketed, a medical device must comply with the general safety and performance requirements applicable to it.

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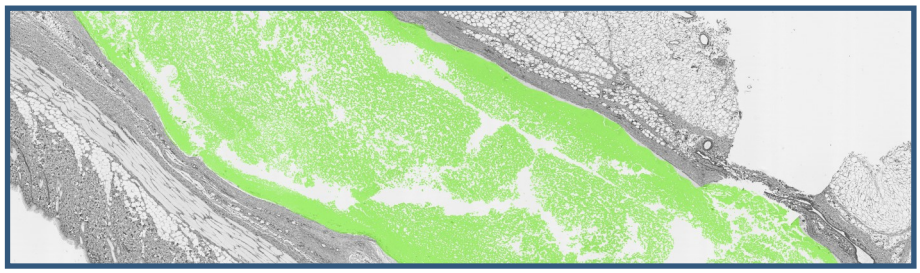
The placing on the market of medical devices is carried out under the responsibility of their manufacturer after they have affixed the CE marking, attesting to compliance with the essential health and safety requirements laid down by the European Directives. Evaluation of the benefit/risk ratio relating to a medical device in a medical intention is different from that of a device used solely for aesthetic purposes such as products for wrinkles treatment. Although the benefit linked with a device in a medical application is objective, measurable and has a direct impact on the patient's health. The characteristic "Invasive" and their wide involvement in healthy subjects suggest potential complications. Consequently, these devices must be strictly monitored by the health authorities in terms of market and vigilance checks.

The manufacturers are committed to implementing the necessary corrective actions in order to comply with the regulations. The healing of wounds, caused by the creation of discontinuities in body tissue through physical, chemical or mechanical processes, involves the migration of inflammatory cells, the synthesis of granulation tissue, the deposition of collagen and proteoglycans and the development of healing. Macroscopic analysis follow the appearance of the wounds and the evolution of the cicatrization whereas microscopic analysis on histologic sections provide the majority of information on presence of hemorrhage, clot (surface and composition), arterial and venous dilatation, presence of granulation tissue and dilation of the lymphatics. Other parameters like infiltration by inflammatory cells (nature and semi-quantitative evaluation), epithelial regeneration (semi-quantitative observation or counting of the number of active cells), formation of Collagen neofibrils (semi-quantitative evaluation) and neovascularization (semi-quantitative study) are of great interest. In addition, histological studies will be able to inform on the product classification mainly according to their persistence in the body: resorbable products (3-6 months), slowly resorbable (6 - 24 months), no resorbable (definitive). To perform histological studies, the samples are predominantly colored at hemalun-eosin even if other more specific stains are also used such as the Ki67 which can detect cells in the process of multiplication or the red Picrosirius that allows better visualization of collagen fibers.



Hyaluronic implant degradation on rat skin explant. Staining quantification 56.3% .

Histalim provides a scientific and technical expertise to assist cosmetic and dermatology professionals for their product validation processes and offers image analysis tools making it possible to validate easily and reliably all types of claims.