

Abstract

In Europe, medical devices are regulated by a community directive, the Medical Devices Directive 93/42, the 42nd directive issued by the European economic community in 1993. To obtain the CE mark a medical device must be security and efficacy. In my thesis work I didn't deal with security tests but with efficacy ones.

The effectiveness analysis of the Oneyonis device consists of several parts:

1. Equivalence with Peak PlasmaBlade by Medtronic
→ Evaluation of the state of the art
2. Pre-clinical animal model efficacy
→ Evaluation of clinical benefit in humans. It was decided to use pre-clinical models and not human being, as these models are significant.

For the demonstration of equivalence are considered:

- Clinical features: same clinical conditions (same medical indication), same intended purpose, at the same site in the body, similar population, not expected to provide significantly different performance.
- Biological characteristics: same materials or substances in contact with the same human tissues or body fluids.
- Technical characteristics: similar design, same conditions of use, similar specifications and properties, similar implementation methods, similar operating principles and critical performance requirements.

The demonstration of effectiveness of the Oneyonis device was achieved through the application of the 3R Method, the goal was to achieve valid scientific results with less sacrifice of animal lives.

The 3R principle (replace, reduce, refine) has its origins with William M. S. Russell & Rex L. Burch, who published their "Principles of Humane Experimental Technique" in 1959. These principles are regarded internationally as the guideline for avoiding or reducing animal experiments and the suffering of laboratory animals:

1. Replacement: replacement of animal experiments by methods that do not involve animals
2. Reduction: reduction in the number of animals in unavoidable animal experiments
3. Refinement: improvement in experimental procedures, so that unavoidable animal experiments.

In-vivo tests: the purpose of this study is to confirm the safety and efficacy of the Oneyonis device on an animal model: model of rescue and selection of soft tissues during ovariectomy. Female rabbits undergo ovariectomy and primary safety endpoints and primary efficacy endpoints are analysed. Histological examinations were also examined to assess (right ovary margin, left ovary margin).

The ovariectomy was chosen for two main reasons:

1. Involves the resection of a non-fatal anatomical part for the life of the rabbit,
2. Allows to have tissue on which to make histological analysis. After the resection the ovaries were fixed in formalin, paraffin processed and stained with haematoxylin and eosin. All specimens were reviewed by one pathologist.

Ex-vivo tests: the aim of this study is to confirm the efficacy of the Oneyonis device on an ex-vivo animal model: model of surgical incision, termination and sectioning of soft tissues. Moreover, the purpose is to confirm the indications of use in terms of tables of delivered power and types of fabric to be treated.