

COMMISSION DIRECTIVE 2005/50/EC

of 11 August 2005

on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹⁾, and in particular Article 13(1)(b) thereof,

Having regard to the request submitted by France and the United Kingdom,

Whereas:

- (1) On the basis of the classification rules set out in Annex IX to Directive 93/42/EEC, total joint replacements are class IIb medical devices.
- (2) France and the United Kingdom requested the classification of total joint replacements as class III medical devices by way of derogation from the provisions of Annex IX to Directive 93/42/EEC, in order to ensure an appropriate conformity assessment of total joint replacements before their placing on the market.
- (3) Conformity assessment is based on a number of elements such as a proper classification, the designation and monitoring of the notified bodies and the proper implementation of the conformity assessment modules as described in Directive 93/42/EEC.
- (4) Reclassification by derogation to the classification rules set out in Annex IX to Directive 93/42/EEC is indicated where the shortcomings identified due to the specific characteristics of a product will be more properly addressed under the conformity assessment procedures corresponding to the new category.
- (5) Hip, knee and shoulder replacements should be distinguished from other total joint replacements, due to the particular complexity of the joint function to be restored and the consequent increased risk of failure due to the device itself.
- (6) In particular, hip and knee replacements are weight-bearing and extremely sophisticated implants, for which the risk of revision surgery is significantly greater than for other joints.

- (7) Shoulder implants are a more recent technique, which are subject to similar dynamic forces; their possible replacement is in principle connected with serious medical problems.
- (8) Furthermore, hip, knee and shoulder replacement surgery is increasingly taking place on young people with a high life expectancy; consequently, the need for such implants to function properly over the life expectancy of the patients and to reduce revision surgery and its risks has been increased.
- (9) Specific clinical data, including long term performance data are not always available for hip, knee and shoulder replacements before they are placed on the market and put into service; consequently, conclusions on clinical data collected by the manufacturer in the framework of the evaluation of the conformity of these products with the requirements concerning their characteristics and performance referred to in Sections 1 and 3 of Annex I to Directive 93/42/EEC should be subject to particular attention and examination in order to verify the appropriateness of the clinical data available.
- (10) Total joint replacements can be subject to multiple modifications following their introduction into clinical use and placing on the market, as shown by hip and knee replacements on the market. However, experience has shown that what appear at first sight to be minor post-marketing changes to the design of previously trouble-free replacements can lead to serious problems due to unintended consequences, which may lead to early failure and major safety concerns.
- (11) In order to achieve the optimal level of safety and health protection and to reduce the design related problems to the lowest level, the design dossier of hip, knee and shoulder replacements, including the clinical data used by the manufacturer to support the claimed performance and the subsequent post-marketing design and manufacturing changes should be examined in detail by the notified body before these devices are introduced in general clinical use.
- (12) Consequently, the notified body should, under the full quality assurance system, effectively carry out an examination of the design dossier and of the changes to the approved design in accordance with point 4 of Annex II to Directive 93/42/EEC.
- (13) For these reasons, it is necessary to proceed to the reclassification of hip, knee and shoulder total joint replacements as class III medical devices.

⁽¹⁾ OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

- (14) It is necessary to provide for an adequate transitional period for hip, knee and shoulder total joint replacements already assessed as class IIb medical devices under the full quality assurance system of Annex II to Directive 93/42/EEC, allowing for their complementary assessment under point 4 of Annex II to the Directive.
- (15) Hip, knee and shoulder total joint replacements already certified following the procedure relating to the EC type examination set out in Annex III to Directive 93/42/EEC, coupled with the procedure relating to the EC verification set out in Annex IV or the procedure relating to the EC declaration of conformity set out in Annex V to that Directive, are not affected by the present Directive as these certification schemes are the same for both class IIb and class III medical devices.
- (16) It is necessary to provide for an adequate transitional period for hip, knee and shoulder total joint replacements that have already been subject to the procedure relating to the EC type examination under Annex III to Directive 93/42/EEC coupled with the procedure relating to the EC declaration of conformity set out in Annex VI to that Directive, allowing for their assessment under Annex IV or Annex V to Directive 93/42/EEC.
- (17) The measures provided for in this Directive are in accordance with the opinion of the Committee on Medical Devices set up by Article 6(2) of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices ⁽¹⁾,

HAS ADOPTED THIS DIRECTIVE:

Article 1

By way of derogation from the rules set out in Annex IX to Directive 93/42/EEC, hip, knee and shoulder replacements shall be reclassified as medical devices falling within class III.

Article 2

For the purpose of this Directive, a hip, knee or shoulder replacement means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint. Ancillary components (screws, wedges, plates and instruments) are excluded from this definition.

⁽¹⁾ OJ L 189, 20.7.1990, p. 17. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council.

Article 3

1. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to Article 11(3)(a) of Directive 93/42/EEC before 1 September 2007 shall be subject to a complementary conformity assessment under point 4 of Annex II to Directive 93/42/EEC leading to an EC design examination certificate before 1 September 2009. This provision does not preclude a manufacturer from submitting an application for conformity assessment based on Article 11(1)(b) of Directive 93/42/EEC.
2. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to Article 11(3)(b)(iii) of Directive 93/42/EEC before 1 September 2007 may be subject to a conformity assessment as class III medical devices pursuant to Article 11(1)(b)(i) or (ii) before 1 September 2010. This provision does not preclude a manufacturer from submitting an application for conformity assessment based on Article 11(1)(a) of Directive 93/42/EEC.
3. Member States shall accept until 1 September 2009 the placing on the market and the putting into service of hip, knee and shoulder replacements covered by a Decision in accordance with Article 11(3)(a) of Directive 93/42/EEC issued before 1 September 2007.
4. Member States shall accept until 1 September 2010 the placing on the market of hip, knee and shoulder replacements which are covered by a Decision in accordance with Articles 11(3)(b)(iii) of Directive 93/42/EEC issued before 1 September 2007 and permit such total joint replacements to be put into service beyond that date.

Article 4

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 March 2007. They shall immediately inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference at the time of their official publication. Member States shall determine how such a reference is to be made.

Member States shall apply those provisions from 1 September 2007.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 5

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 11 August 2005.

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For the Commission

Günter VERHEUGEN

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