

2007-02-15

Medical Products Agency requests additional information from Nobel Biocare AB

The Medical Projects Agency has reviewed Nobel Biocare's plan for taking measures to improve their instructions for use for the NobelDirect and NobelPerfect dental implants. The Medical Projects Agency now requests additional information from Nobel Biocare AB.

Earlier, the Medical Products Agency's investigation of the dental implants indicated that the instructions for use for NobelDirect and NobelPerfect implants were inadequate. The authority demanded that Nobel Biocare AB describe their planned informational activities to implement improvement of the instructions.

The Medical Products Agency (MPA) has reviewed Nobel Biocare's plan. The review has resulted in a number of questions that Nobel Biocare shall respond to by 13 March 2007 at the latest. The MPA has pointed out three important issues in particular

- The correct placement of the implant when it is inserted without exposing the jawbone, also called the flapless technique
- The dangers of mechanical processing of the implant before complete healing, and,
- The company's estimation of the skills required before a dentist or dental surgeon begins using the dental implants.

The MPA's earlier decision holds fast. Nobel Biocare AB may not actively market the dental implants until their informational activities in the final approved plan are completed.

More information

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