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Continue sales – but with certain restrictions

The Swedish Medical Products Agency investigation of the dental implants NobelDirect and NobelPerfect show that there can be deficiencies in the instructions for use for the products. The Medical Products Agency has ordered the company Nobel Biocare to clarify certain information in the information materials for the products.

The Medical Products Agency (MPA) presented the results of the investigation of the NobelDirect and NobelPerfect dental implants at a press conference in Uppsala, Sweden on Wednesday. The investigation showed that there can be shortcomings in the instructions for use, something that can explain the raised risk for breakdown of the jawbone that has been observed for the dental implants. Therefore, the MPA has taken the decision to demand information activities of Nobel Biocare.

The MPA decision directs Nobel Biocare to clearly describe possible causes for the breakdown of the jawbone in the instructions for use and training programs. In addition, the company must describe how the risk for breakdown can be avoided. In sales and promotion information and instructions for use, the company shall indicate the user qualifications and skills required so that a dentist can use the implants safely. The company must inform customers and authorities for medical devices in the countries concerned of the new rules that apply.

Nobel Biocare shall report to the MPA no later than 8 January 2007 with a plan for carrying out the information activities. If the company does not report within the specified time, the MPA may decide to ban NobelDirect and NobelPerfect from the market.

Nobel Biocare may not actively market the dental implants until the information activities are carried out.

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