



New Device Approvals

Carisolv Non-Invasive Caries Removal System - P000005

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Carisolv Non-Invasive Caries Removal System
Manufacturer: Medi Team AB
Address: Goteborgsvagen 74, SE-433 63
Approval Date: June 27, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p000005a.pdf>

What is it? Carisolv is a combination of chemicals for softening and partially removing decayed dentin (dentin caries). Dentin is the slightly yellow material that makes up most of the tooth. A hard, outer layer of enamel surrounds the dentin. Dentin is much more vulnerable to decay than the enamel.

How does it work? The Carisolv System is mixed into a gel, and then applied to the decayed tooth. The gel softens the hard decayed material so that it can be partially removed with hand instruments. The decay that cannot be removed with hand instruments is then removed with a dental drill.

When is it used? Since Carisolv minimizes use of the dental drill, it is an option for patients who may be anxious about drilling procedures.

What will it accomplish? Carisolv will partially remove some dental caries from a tooth and allow the dentist to slightly reduce the amount of time spent using the dental drill. According to the manufacturer, there are no side effects.

When should it not be used? "The manufacturer states that there are no contraindications."

Additional information: The SSED and Labeling will be available at:
<http://www.fda.gov/cdrh/pdf/p000005.html>

Other: NIH

<http://medlineplus.nlm.nih.gov/medlineplus/ency/article/001055.htm#treatment>

http://odp.od.nih.gov/consensus/news/releases/115_release.htm

(Updated 10/3/2001)