



New Device Approvals

SUPARTZ™ DISPO- P980044

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: SUPARTZ™ Dispo
Manufacturer: SEIKAGAKU Corporation
Address: 1-5, Nihonbashi-honcho 2-chome, Chuo-ku, Tokyo 103-0023 Japan
Approval Date: January 24, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p980044a.pdf>

What is it? SUPARTZ is a solution of sodium hyaluronate. It is injected into knee joints to relieve pain from osteoarthritis.

When is it used? Natural sodium hyaluronate lubricates knees, but in patients with osteoarthritis, natural sodium hyaluronate does not work effectively. SUPARTZ is used when simple painkillers and exercise and physical therapy fail to relieve knee pain from osteoarthritis.

What will it accomplish? Most patients will experience less pain after 5 weekly injections.

When should it not be used?

- If a patient is allergic to sodium hyaluronate,
- If there is an infection or skin disease at the injection site,
- If the patient is allergic to products from birds, such as feathers, eggs or poultry,
- If a patient is pregnant or lactating or,
- In children

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p980044.html>

(updated 3/6/01)