STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

Notification of decisions etc.

64.—(1) Any decision taken by a UK notified body, the Secretary of State or any other enforcement authority pursuant to these Regulations to withdraw a device from the market, or to prevent or restrict a device being placed on the market, put into service or made available, shall be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available, and that person shall be informed—

(a) of the grounds on which the decision is based;

(b) of the legal remedies available to that person and of any time limits which apply to their exercise; and

(c) if the applicant was not entitled under the 1987 Act to make representations in respect of the decision, that the decision maker will, on request, review the decision and in the course of so doing will give him or his authorised representative an opportunity to make representations in respect of the decision.

(2) Except in cases where urgent action is justified (in particular by public health requirements), if a UK notified body, the Secretary of State or any other enforcement authority is considering making a decision referred to in paragraph (1), they or he shall give the manufacturer or his authorised representative an opportunity to make representations to them or him before the decision is taken.