apply only if the menstrual pad is made from cotton or rayon and the body contact material(s) are safety tested for dermal irritation, dermal sensitivity, acute toxicity, and mucosal irritation. Finally, the proposed exemption for the therapeutic vaginal douche apparatus (§ 884.5900 (21 CFR 884.5900)) is limited and would apply only to devices which operate by gravity feed.

TABLE 13.—OPHTHALMIC DEVICES

CFR section	Device
886.1405	Ophthalmic trial lens set.
886.1750	Skiascopic rack.
886.1760	Ophthalmic refractometer.
886.3200	Artificial eye.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 13 above. The proposed exemption for the artificial eye (§ 886.3200 (21 CFR 886.3200)) is limited and would apply only to devices made of the same materials, have the same chemical composition, and use the same manufacturing and disinfection processes as currently legally marketed devices.

TABLE 14.—ORTHOPEDIC DEVICES

CFR section	Device
888.1100	Arthroscope.
888.3000	Bone cap.
888.5960	Cast removal instrument.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 14 above. The proposed exemption for the arthroscope (§ 888.1100 (21 CFR 888.1100)) is limited and would apply only to the following manual arthroscope instruments: Cannulas, curettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knot pushers, suture punches, switching rods, and trocars.

TABLE 15.—PHYSICAL MEDICINE DEVICES

CFR section	Device
890.1575	Force-measuring platform.
890.1600	Intermittent pressure measurement system.
890.1615	Miniature pressure transducer.
890.3175	Flotation cushion.

TABLE 15.—PHYSICAL MEDICINE DEVICES—Continued

CFR section	Device
890.3760	Powered table.
890.5380	Powered exercise equipment.
890.5410	Powered finger exerciser.
890.5660	Therapeutic massager.
890.5925	Traction accessory.
890.5940	Chilling unit.
890.5950	Powered heating unit.
890.5975	Therapeutic vibrator.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 15 above.

TABLE 16.—RADIOLOGY DEVICES

CFR section	Device
892.1700	Diagnostic x-ray high voltage generator.
892.1760	Diagnostic x-ray housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiologic patient cradle.
892.1880	Wall-mounted radiographic cassette holder.
892.5780	Light beam patient position indicator.
892.6500	Personnel protective shield.

FDA is proposing to grant an exemption from the requirement of premarket notification for each of the devices listed in Table 16 above. The proposed exemption for the personnel protective shield (§ 892.6500 (21 CFR 892.6500)) is limited and would only apply to devices whose labeling specifies the lead equivalence.

V. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. The Device Priority Model: Development and Applications, Office of Standards and Regulations, FDA, Rockville, MD, October 1989.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment or an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a proposal on small entities. Because this proposal would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements or premarket notification, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VIII. Request for Comments

Interested persons may, on or before October 11, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.