A. Comments Addressing Specific Devices

1. One comment opposed the proposed exemptions from the requirement of premarket notification for the retentive and splinting pin (§ 872.3740) and the root canal post (§ 872.3810). According to this comment, premarket notification submissions are necessary to ensure that the material used in these devices are biocompatable in order to prevent toxicity and/or allergic reactions. The comment also stated that, because teeth are delicate, these devices must be designed so that no undue stress will be imparted upon the teeth. According to this comment, exempting these devices from premarket notification would result in substandard products being made available to dental professionals. Another comment in favor of the exemption disagreed, stating that it is the ''method of use and application'' of these devices, not the design or materials used in them that is the determining factor in the safe and effective use of these devices. Moreover, according to this comment, data relating to these devices demonstrate that these devices are well-known, established, safe, and effective.

FDA has concluded that exempting these devices from the requirement of premarket notification will not result in the marketing of substandard devices. First, both devices have a long history of safe use. Second, neither device has a history of adverse events. Third, literature indicates little potential for any danger to public health. Finally, the device identifications clearly describe the material composition of these devices. If devices are made of materials other than those described in the identification, they will be classified into another generic type of device or remain in the same generic type of device, but not be exempt from the requirements of premarket notification.

2. A comment requested that the proposed exemption for carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (§ 872.3490) be expanded to include other double salts of polyvinylmethylether maleic acid, specifically salts involving those ions that achieve the same technical effect as calcium and sodium, i.e., iron, magnesium, zinc, and potassium.

FDA disagrees with this comment. Although the comment refers to carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (§ 872.3490), a class I device, the comment is actually requesting FDA to exempt another classified dental adhesive device, polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive (§ 872.3500) which is a class III device.

3. FDA received a comment requesting that an endolumina illuminated bougie (EIB) device, a silicone elastomer coated fiberoptic bundle designed to aid in the identification of the esophagus, rectum, rectosigmoid, and other organs during surgical procedures, be added to the list of class II, tier 1 devices to be proposed for exemption from the requirement of premarket notification in a future issue of the **Federal Register**.

FDA disagrees with this comment. As stated in the July 21, 1994, proposal, in early 1994, FDA's Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources for the review process. Under this risk assessment, all class I, class II, and class III devices were placed into one of three tiers based upon the inherent risk associated with each device. Tier 3 devices include all first and second of a kind devices utilizing new technology or having new intended uses(s), as well as other devices determined by their inherent risk to require an intensive review. These tier 3 devices require intensive scientific and labeling review by a review team as well as advisory panel input. Tier 2 devices include devices which require routine scientific and labeling review. This tier encompasses the majority of 510(k)'s and select premarket approval applications. Tier 1 devices include, among other things, devices which have a minimal inherent risk and whose review focuses upon intended use.

FDA had found EIB to be substantially equivalent to both the gastroenterology-urology fiberoptic retractor (§ 876.4530), a class I device and the class I transilluminator (§ 886.1945). However, upon further consideration, FDA now believes that EIB would have been more appropriately classified under the fiberoptic light ureteral catheter (§ 876.4020), a class II device, which is also a fiberoptic bundle that emits light, but is inserted into the ureter to enable it to be seen during lower abdominal or pelvic surgery. While the specific indication statement for these two devices are different, their intended uses are the same and, therefore, the devices are substantially equivalent. Like the fiberoptic light ureteral catheter, EIB is used with a high intensity light source, which could produce heating and potential damage of body tissues. Concerns identified at the time of classification of the fiberoptic light ureteral catheter included thermal burns related to the amount of energy transmitted. For this reason, FDA has placed the fiberoptic light ureteral catheter in class II, tier 2. Additionally, endoscopes (which could have been another predicate) and esophageal dilators (which include the esophageal bougie) are also tier 2 devices. Furthermore, retaining the EIB device in class II, tier 2 is justified because EIB is a one-of-a-kind device. FDA has not yet had sufficient experience with this device to justify a tier 1 premarket review, i.e., a focused labeling review for intended use/indications for use. For the reasons stated above, the EIB device will remain a class II, tier 2 device.

B. Comments Requesting FDA to Expand the Exemption from the Requirement of Premarket Notification to Include an Additional 56 Devices

4. A total of eight comments requested that the 56 devices listed in Table 4 also be exempted from the requirement of premarket notification.

TABLE 4

21 CFR	Device
862.2230	Chromatographic separation material for clinical use.
862.2250	Gas liquid chromatography system for clinical use.
866.2600	Wood's fluorescent lamp.
868.1930	Stethoscope head.
872.3310	Coating material for resin fillings.
872.3730	Pantograph.
872.3820	Root canal filling resin.
872.4200	Dental handpiece and accessories.
872.5470	Orthodontic plastic bracket.
872.5500	Extraoral orthodontic headgear.
872.6050	Saliva absorber.
872.6390	Dental floss (including devices made of any inert materials).
872.6770	Cartridge syringe.
874.1060	Acoustic chamber for audiometric testing.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.
874.4770	Otoscope.
874.5220	Ear, nose, and throat drug administration device.
874.5800	External nasal splint.
876.4890	Urological table and accessories (manually powered).
876.5160	Urological clamp for males.
876.5250	Urine collector and accessories (not connected to indwelling catheter).
878.4040	Surgical apparel (except surgical gowns and masks).
878.4460	Surgeon's gloves.
880.5110	Hydraulic adjustable hospital bed.