

**EXEMPTIONS OF DENTAL DEVICES FROM PREMARKET NOTIFICATION  
AND GOOD MANUFACTURING PRACTICES--510(k) AND GMP--REQUIREMENTS**

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 Vol. 59, No. 234, Dec. 7, 1994, pp. 63005-015  
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 Vol. 65, No. 10, Jan. 14, 2000, pp. 2296-2323  
 Vol. 65, No. 63, Mar. 31, 2000, pp. 17138-148

	<u>EXEMPT FROM:</u>		<u>CODE</u>
	<u>510(k)</u>	<u>GMP*</u>	
1. 872.1500 Gingival fluid measurer	X		JEO
2. 872.1730 Electrode gel for pulp tester	X		EAS
3. 872.1820 Dental x-ray exposure alignment	X		EHA
4. 872.1840 Dental x-ray position indicator (Coll.)	X		EHB
5. 872.1850 Lead-lined position indicator	X		EAH
6. 872.1905 Dental x-ray film holder	X	X	EGZ
7. 872.3080 Mercury and alloy dispenser	X	X	EHE
8. 872.3100 Dental amalgamator (AC powered)	X		EFD
9. 872.3110 Dental amalgam capsule	X		DZS
10. 872.3130 Preformed anchor	X		EJX
11. 872.3140 Resin applicator	X	X	KXR
12. 872.3150 Articulator	X	X	EJP
13. 872.3165 Precision attachment	X		EGG
14. 872.3220 Facebow	X	X	KCR
15. 872.3240 Dental bur	X		EJL
16. 872.3275 Dental Cement (zinc oxide-eugenol)	Xwl		EMB
17. 872.3285 Preformed clasp	X		EHP
18. 872.3330 Preformed crown	X		ELZ
19. 872.3350 Gold or stainless steel cusp	X		ELO
20. 872.3360 Preformed cusp	X		EHQ
21. 872.3400 Karaya and sodium borate denture adhesive	Xwl		KOR
22. 872.3410 Eth. oxide & CMC denture adhesive	X		KOL
23. 872.3450 Eth. oxide & karaya denture adhesive	X		KXX
24. 872.3490 CMC+PVME denture adhesive	X		KOO
25. 872.3520 OTC denture cleanser	X		EFT
26. 872.3530 Mechanical dental cleaner	X		JER
27. 872.3540 OTC denture cushion or pad	Xwl		EHR
28. 872.3580 Preformed gold denture tooth	X		ELN
29. 872.3670 Resin impression tray material	X	X	EBH
30. 872.3730 Pantograph	X	X	KCS

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(Continued)**

31. 872.3740 Retentive and splinting pin	X		EBL
32. 872.3810 Root canal post	X		ELR
33. 872.3830 Endodontic paper point	X		EKN
34. 872.3840 Endodontic silver point	X		EKL
35. 872.3850 Gutta percha	X		EKM
36. 872.3900 Posterior artific. tooth, metal	X		ELJ
37. 872.3910 Backing, facing for artific. tooth	X		ELK
38. 872.3980 Endosseous dental implant accessories	X		NDP
39. 872.4130 Intraoral dental drill	X		DZA
40. 872.4535 Dental diamond instrument	X		DZP
41. 872.4565 Dental hand instrument	Xwl	EIL,EJB,EKD,etc	
42. 872.4620 Fiber optic dental light	X		EAY
43. 872.4630 Dental operating light	X		EAZ
44. 872.4730 Dental injecting needle	X		DZM
45. 872.5410 Orthodontic appliance and accessories	X		EJF
46. 872.5525 Preformed tooth positioner	X		KMY
47. 872.5550 Teething ring (solid)	X		MEF
48. 872.6010 Abrasive device and accessories	X	X	EHJ, EHL
49. 872.6030 Oral cavity abrasive polish agent	X		EJR
50. 872.6050 Saliva absorber	X	X	KHR
51. 872.6100 Anesthetic warmer	X		EFC
52. 872.6140 Articulation paper	X	X	EFH
53. 872.6200 Base plate shellac	X	X	EEA
54. 872.6250 Dental chair (without operative unit)	Xwl		KLC
55. 872.6290 Prophylaxis cup	X	X	EHK
56. 872.6300 Rubber dam and accessories	Xwl		EIE
57. 872.6390 Dental floss	Xwl		JES
58. 872.6475 Heat source for bleaching teeth	X		EEG
59. 872.6510 Oral irrigation unit	X		EFS
60. 872.6570 Impression tube	X	X	KCQ
61. 872.6640 Dental operative unit (accessories tray exempt)	Xwl		EIA
62. 872.6650 Massaging pick or tip for oral hygiene	X	X	JET
63. 872.6670 Silicate protector	X	X	EFX
64. 872.6855 Manual toothbrush	X	X	EFW
65. 872.6865 Powered tooth brush	X		JEQ
66. 872.6870 Disposable fluoride tray	X	X	KMT
67. 872.6880 Preformed impression tray	X	X	EHY
68. 872.6890 Intraoral dental wax	X	X	EGD
69. 868.5820 Dental protector**	X		BRW

"wl" means with limitations

\* Unless Sterile

\*\* This "dental" device, classified with anesthesiology devices, is also exempt.