



(benefit* risk*) NEAR device*

✕ →

SmartSearch Filters

FDA Regulation (21 CFR/Guidance)

CFR (15)

▼

FDA Agency (CBER/CDRH/CDER)

Select value

▼

FDA Search Results Shown Below

[FDA Regulation (21 CFR/Guidance) = "CFR"]

15 results for '(benefit* risk*) NEAR device*'

Click to Sort SmartSearch Results

▼

↑



[Subpart D - De Novo Classification](#)
Procedures for review of a De Novo request.
Sec. 860.240(c)(1)

[Subpart D - Prosthetic Devices](#)

Tympanic membrane contact hearing aid.

Sec. 874.3315(b)(5)(v)(C)

[Subpart F - Therapeutic Devices](#)

External upper esophageal sphincter compression device.

Sec. 874.5900(b)(6)(iii)

[Subpart F - Therapeutic Devices](#)

Urethral insert with pump for bladder drainage.

Sec. 876.5140(b)(7)(v)

[Subpart F - Therapeutic Devices](#)

Rectal control system.

Sec. 876.5930(b)(7)(iii)

[Subpart F - Therapeutic Devices](#)

Rectal control system.

Sec. 876.5930(b)(7)(iv)

**Email**

21 CFR §860.3 - Classification of devices intended for human use into one of three regulatory classes: class I, class II, and class III

21 CFR Part 860 - Medical Device Classification Procedures

These are the clauses in 21 CFR 860 that reference benefit vs risk assessment for medical devices. Is there anything

03:55

Give me only 21 CFRs from list above that deal with retina or eye

04:07

1. 21 CFR Part 812 - Investigational Device Exemptions (IDEs): Guidance for Sponsors, Clinical Investigators, and IRBs
2. 21 CFR §812.119 - Changes to an approved investigational device exemption
3. 21 CFR Subpart D - Humanitarian Device Exemptions (HDEs): Guidance for Industry and Food and Drug Administration Staff
4. 21 CFR §860.1 - Scope and Application
- 5.

04:07

 Reply to GPT-3

