[Your Company's Letterhead]
[Date]
[Recipient's Name]
[Recipient's Title]
[Recipient's Organization]
[Recipient's Address]
[City, State, Zip Code]

Dear [Recipient's Name],

Subject: FDA Approval Letter for [Device Name] (KXXXXXXXX)

We are pleased to inform you that the [Device Name] has been granted FDA clearance under 510(k) process, with the reference number KXXXXXXXX. This approval is effective as of [Approval Date].

[Device Name] is indicated for [brief description of intended use]. The FDA has determined that the device is substantially equivalent to the predicate device(s), identified as [Predicate Device Name(s)], under the criteria established by section 513(i) of the Federal Food, Drug, and Cosmetic Act.

The following conditions apply to the approval:

1. [Condition 1: stipulations, if any]
2. [Condition 2: stipulations, if any]
3. [Condition 3: stipulations, if any]

It is important to ensure compliance with all FDA regulations during the marketing and distribution of the [Device Name]. Please maintain all records related to the operation and manufacturing of the device for FDA review, if required.

For any inquiries or further information, please do not hesitate to contact our regulatory affairs department at [contact information].

Congratulations on this achievement, and we look forward to seeing [Device Name] make a positive impact in the medical field.

Sincerely,
[Your Name]
[Your Title]
[Your Company]
[Your Phone Number]
[Your Email Address]
[Enclosures: if any]