**ภาคผนวก 5**

**Marketing History Declaration Template**

(To be printed on Company Letterhead of Applicant)

Medical Device Control Division

Thai Food and Drug Administration

Ministry of Public Health

*[Date]*

Dear Sir/Madam,

I, *[name of Company]*, the applicant for registration of the medical device(s) stated below, hereby declare that the medical devices have been marked in the *two independent reference regulatory agencies’* jurisdiction for at least one year. The first dates of market introduction in *[jurisdiction/country]* and *[jurisdiction/country]* were *[mm/yyyy]* respectively

This declaration shall apply to the following medical device(s):

*[List containing product names of medical devices]*

I, the applicant, am aware that marking a declaration which I know to be false is an offence under the Medical Device Act (B.E.2008), Medical Device Act (2nd edition B.E.2562) and other applicable laws that may be in forced. I acknowledge that any non-compliance with any registration condition issued by the Thai Food and Drug Administration in relation to medical devices registered with the Medical Device Control Division may result in the suspension or cancellation of the medical devices registration.

Yours Sincerely,

*[Signature]*

*[Full Name and Title of Senior Company Office]*

*[Company stamp]*