國立清華大學 102 學年度碩士班考試入學試題

系所班組別：0519 奈米工程與微系統研究所、
0514 動力機械工程學系碩士班 丁組(設計、製造組)

考試科目（代碼）：1902 科技英文、1402 科技英文

 *請在【答案卷、卡】作答

Part I. There are 15 problems in this Part. 30% ***Part I*** 第 1～15 題請作答於答案卡

The following is part of TIME Magazine's "Time's Person of the Year--2006" article.

The "Great Man" theory of history is usually attributed to the Scottish philosopher Thomas Carlyle, who wrote that "the history of the world is but the biography of great men." He believed that it is the few, the powerful and the famous who shape our collective destiny as a species. That theory took a serious beating this year. ...
The tool that makes this possible is the World Wide Web. Not the Web that Tim Berners-Lee hacked together (15 years ago, according to Wikipedia) as a way for scientists to share research. It's not even the overhyped dotcom Web of the late 1990s. The new Web is a very different thing. It's a tool for bringing together the small contributions of millions of people and making them matter. Silicon Valley consultants call it Web 2.0, as if it were a new version of some old software. But it's really a revolution....But that's what makes all this interesting. Web 2.0 is a massive social experiment, and like any experiment worth trying, it could fail. There's no road map for how an organism that's not a bacterium lives and works together on this planet in numbers in excess of 6 billion.

1. 〔 〕 Time Magazine thinks in 2006:
   (A) History is a record of great men.
   (B) History is longer the record of great men.
   (C) History will record Web 2.0
2. 〔 〕 Web. 2.0 is
   (A) a new protocol
   (B) a new software
   (C) an old software
3. 〔 〕 When it says, "an organism that's not a bacterium lives and works together on this planet in numbers in excess of 6 billion", it means:
   (A) Web 2.0 websites
   (B) Computer virus
   (C) People

4. 〔 〕The phrase "Web 2.0" came from:
   (A) IBM
   (B) Microsoft
   (C) California
5. 〔 〕Web 2.0
   (A) will succeed.
   (B) may fail
   (C) will double in 2007

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6. 〔 〕_____surface plasmon resonance, more and more approaches towards the high-precision fabrication of nano antennas have been explored.
   (A) Base on
   (B) Base at
   (C) Based on
   (D) Basing on
   (E) Basis of
7. 〔 〕Not only the resolution but also the sensitivity ____ greatly enhanced.
   (A) is
   (B) are
   (C) were
   (D) be
   (E) being
8. 〔 〕The ____ he gave was invaluable to me at this early stage of my career.
   (A) advice
   (B) advise
   (C) advisory
   (D) advising
   (E) adviser
9. 〔 〕A doctor cannot treat an illness until he or she has made a _____.
   (A) diagonal
   (B) diagnose
   (C) diagnosis
   (D) diagnoses
   (E) diagnostic

10. 〔 〕Cantilever beams are suspended ____ the removal of the sacrificial layer.
(A) since
(B) before
(C) after
(D) because
(E) due

11. 〔 〕Jupiter, the fifth planet from the Sun and the largest planet within the Solar System, has ____ solid surface and is primarily composed of hydrogen with a small proportion of helium.
(A) not
(B) nor
(C) no
(D) neither

12. 〔 〕Built in 1882, the Kinzua Viaduct in McKean County is open only to those visitors ____ are able to walk its 2,058-foot length.
(A) who
(B) to whom
(C) which they
(D) that which

13. 〔 〕Silicon nitride etching follows the same sequence of operations ____ etching.
(A) That silicon dioxide
(B) Where silicon dioxide
(C) Silicon dioxide
(D) As silicon dioxide

14. 〔 〕____ unstable and explodes as a supernova is not known.
(A) For a star to become
(B) A star becones
(C) How a star becomes
(D) That a star is becoming

15. 〔 〕A car must be strong enough to support its own weight ____ the weight of the driver and passengers who use it.
(A) as well
(B) so well
(C) as well as
(D) so well as

Part 2. **English Writing (30%)** ***Part 2*** **請作答於答案卷**

What would you expect to obtain while being a graduate student at National Tsing Hua University? Please mention, at least, 5 points about this issue.

Part 3. **Translation (from English to Chinese) (40%)** ***Part 3*** **請作答於答案卷**

Thousands of devices were already marketed in 1976, so Congress included an alternative pathway to the PMA known as the 510(k) provision, which was intended to provide a less burdensome route to enable newer versions of existing devices to enter the market. The 510(k) pathway did not require clinical trials or manufacturing inspections to demonstrate safety and efficacy. Instead, the sponsor was required only to demonstrate that the device was *substantially equivalent* in materials, purpose, and mechanism of action to another device that was already on the market in May 1976. The previous device served as the *predicate* device with which the new one would be compared. This approach was justified as a way to give manufacturers the opportunity to make small improvements on the devices already on the market and to allow companies with new products to compete with very similar devices without using the more extensive PMA process. If the FDA determined that the product was reasonably safe and effective according to the 510(k) review, it was said to be *cleared for market* rather than *approved.*

Former FDA officials explain that in 1976, relatively few medical devices were permanently implanted or intended to sustain life. The 510(k) process was specifically intended for devices with less need for scientific scrutiny, such as surgical gloves and hearing aids. At first, 510(k) reviews were easy for the FDA to conduct because the new devices were so similar to the devices already on the market, but the system was quickly challenged as new devices changed more dramatically and became more complex. The FDA did not have the resources to develop performance standards for new moderate-risk devices or to shift more devices to the much more stringent and time-consuming PMA process. Instead, the opposite trend occurred. In an era of aggressive deregulation, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was passed by Congress, signed by President Bush, and interpreted by the FDA to shift the regulatory standard to "the least burdensome approach in all areas of medical device regulation." Subsequently, the definition of *substantially equivalent* was modified to include products made from different materials and using a different mechanism of action if they were determined to have a similar safety profile. Since clinical trials are not required for

510(k) clearance, approval of devices would be based on biomaterials testing or other

standards. Furthermore, predicate devices no longer were limited to products already on the market prior to May 1976 but could include devices cleared through the 510(k) or PMA process. In recent years, the FDA has used the 510(k) provision as the dominant mechanism for new device *clearance*, reviewing only 1% of medical devices by its more rigorous PMA process. The present study was designed to examine how often the different approval or clearance processes were used for medical devices that were subsequently recalled for life-threatening problems.